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Roche

February 20, 2007

*BY HAND DELIVERY AND EMAIL*
*www.cms.hhs.gov/regulations/eRulemaking*

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

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

Dear Acting Administrator Norwalk:

Hoffmann-La Roche Inc. ("Roche") appreciates the opportunity to submit these comments on the proposed rule to implement provisions of the Deficit Reduction Act of 2005 ("DRA") that was published by the Centers for Medicare and Medicaid Services ("CMS") in the *Federal Register* on December 22, 2006.[1] Roche supports CMS's efforts to implement the Medicaid prescription drug provisions of the DRA in a manner that will make the Medicaid drug pricing requirements more cohesive, transparent, and stable. Roche endorses the comments on this proposed rule submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO"), and offers these comments for additional emphasis and as a supplement to the submissions made by those organizations.

Roche understands the challenges CMS faces in advancing the healthcare system for Medicaid beneficiaries so that they receive high-quality services at an appropriate cost. While we generally support most of the efforts proposed by CMS to promote fair drug[2] reimbursement practices, we ask for clarification and guidance regarding the following issues.

## I. Definition of Retail Pharmacy Class of Trade - 42 C.F.R. § 447.504

Roche applauds CMS's efforts to clarify the definition of retail pharmacy class of trade, which is a key component in calculating the Average Manufacturer Price ("AMP"). We offer the

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

[2] The term "drug" refers to both drugs and biologicals.



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following comments on CMS's proposals for the determination of AMP, and in particular on the proposed definition of retail pharmacy class of trade. AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."[3] The proposed rule would define retail pharmacy class of trade as "any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager ("PBM"), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[4] Roche believes that this definition is consistent with the concept, originally suggested by PhRMA, that the "optimum approach [to defining the retail pharmacy class of trade] is to use a function-based analysis that recognizes that the function of an entity in the distribution chain [should] govern whether particular transactions should be included in the calculation of AMP."[5] The proposed definition adds needed specificity but is also flexible enough to accommodate new entities that sell to the general public. However, to ensure consistency of CMS's overarching principle that only entities that are open to the general public be accounted for in AMP, CMS should specify that certain types of retail or mail order pharmacies that do not sell to the general public, such as hospital outpatient pharmacies and in-clinic or closed-walled pharmacies are not included in the retail pharmacy class of trade.

### A. Prices to Other Federal Programs

In the rule's treatment of included and excluded sales and prices for both AMP and Best Price purposes, CMS proposes to exclude, as prices to other federal programs, "[a]ny depot prices (including TRICARE)." Roche agrees that prices to federal programs should be excluded from AMP and Best Price. However, Roche requests that, in the Final Rule, CMS clarify why TRICARE is considered "a depot price."

As CMS may be aware, the Department of Defense's ("DoD") TRICARE health care program provides coverage for prescription drugs through three different delivery systems: the military treatment facility, mail order and retail pharmacy. Under the Veterans Health Care Act ("VHCA"), a "depot contracting system" is as "a centralized commodity management system" through which covered drugs are "procured by" a federal agency. The price controls in the VHCA apply to drugs procured by DoD (and other specified agencies) through a depot contracting system.

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[3] SSA § 1927(k)(1)(A) (emphasis added).

[4] 71 Fed. Reg. at 77196 (proposed 42 C.F.R. pt. 447.504(e)).

[5] See PhRMA comments to the Office of the Inspector General of the Department of Health and Human Services ("OIG") regarding the meaning of "retail pharmacy class of trade" in the OIG Report: "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," No. A-06-06-00063, Appendix F at 3-5 (May 2006).



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In our view, with respect to TRICARE, drugs are procured only by the military treatment facility and mail order pharmacy and thus only those entities can be party to a depot contracting system under the VHCA. Distribution of drugs through the retail pharmacy network does not fall within the statutory definition of a depot contracting system, because drugs dispensed to DoD beneficiaries at retail pharmacies are not procured by DoD (or any other federal agency). Instead, the retail pharmacies acquire those drugs through commercial arrangements between the retail pharmacies and wholesalers. Accordingly, CMS should confirm that sales through the retail pharmacy program are not depot prices for purposes of the Medicaid Rebate Act.

The DoD recently announced that it will consider voluntary rebate proposals from manufacturers covering retail pharmacy sales. Under any such agreements, manufacturers would pay negotiated rebates to DoD for drugs dispensed by retail pharmacies to DoD beneficiaries. In our view, the sales and associated rebates under such agreements would be analogous to the sales and associated rebates in government programs, such as the Medicare Part D program and state pharmaceutical programs, under which the government acts as a third party payor for drugs dispensed by an entity in the retail pharmacy class of trade. Consistent with CMS's proposed approach for dealing with Part D and similar third party payor rebates, therefore, rebates under voluntary agreements should be included in AMP as a price concession.

With respect to Best Price, Roche believes that the prices and any voluntary rebates offered under voluntary rebate agreements with DoD should be excluded from the Best Price determination. However, the exclusion of these prices (net of rebates) should not be based on the statutory exemption for depot prices (because, as noted, there is no procurement by DoD of the drugs that are sold through its retail pharmacy network). Instead, it should be based on the statutory exemption for "any price charged on or after October 1, 1992, to ...the Department of Defense."[6] Any rebates offered to DoD under its voluntary rebate program would be a price concession paid to the DoD relating to covered drugs. Accordingly, we believe this exemption is an appropriate basis for excluding rebates paid to DoD for drugs sold to DoD beneficiaries through the retail pharmacy network. CMS should make this distinction clear in the Final Rule.[7]

### B. Administrative and Service Fees

CMS proposes that manufacturers should include all fees that do not satisfy the definition of a "bona fide service fee" in the calculation of AMP.[8] CMS proposes to define a bona fide service fee as: "a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would

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[6] SSA. Section 1927 (c)(1)(C)(I).

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

[8] 71 Fed. Reg. at 77, 180, 77, 195. Id. at 77, 195, 77, 197-98 (proposed 42 C.F.R. pt. 447.502, .504(i), .505(e)(1)).



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otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not an entity takes title to the drug."[9] The proposed definition is similar to the definition adopted in the ASP final rules.[10] CMS should clarify that recent interpretations in the Medicare Physician Fee Schedule Final Rule[11] of the bona fide service fee definition also apply in the AMP and Best Price context.

In addition to the proposed exception for bona fide service fees, Roche recommends that CMS consider permitting manufacturers to exclude from AMP all fees for services that meet the requirements of the personal services safe harbor to the anti-kickback statute.[12] These safe harbor requirements include sufficient safeguards to insure that any such fees are fair market value for bona fide services.

CMS should also clarify the circumstances under which fees to group purchasing organizations ("GPOs") can be excluded from AMP. Although in the 2007 Medicare Physician Fee Schedule, CMS concluded that fees to GPOs should be excluded from ASP if they meet the definition of bona fide service fees, it would be helpful to have additional guidance on when GPO fees should be excluded from AMP and Best Price calculations.

One approach that Roche supports was previously offered by the Health Industry Group Purchasing Association (the trade association for GPOs). They suggested that fees to GPOs should not be treated as price concessions "unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the group purchasing organization."[13] CMS may also want to clarify that GPO fees do not affect AMP calculations when the GPO negotiates purchase prices for member hospitals for drugs used in the inpatient setting, since the underlying sales to hospitals would be excluded from AMP in this circumstance.

## II. Requirements for Manufacturers - Section 447.510

### A. Base Date AMPs and Reference AMPs

The formula used to calculate Medicaid rebates for innovator drugs requires manufacturers to pay an "additional rebate" equal to the difference between a drug's current AMP and its inflation-adjusted "base date" AMP, which is generally the AMP for the first full quarter in which the drug

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[9] 71 Fed. Reg. 77174 at 77176, 77180.

[10] Id. at 77180.

[11] Medicare Physician Fee Schedule final rule, 71 Fed. Reg. 69624, 69666-8.

[12] 42 C.F.R. § 1001.952(d).

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



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was sold. CMS proposes that manufacturers be allowed to "recalculate base date AMP in accordance with the definition of AMP in § 447.504(e) of this subpart."[14] Thus, CMS recognizes, appropriately in our view, that manufacturers must have the option to adjust base date AMP to account for the changes set forth in the DRA and the Final Rule. Otherwise, the additional rebate amount could increase by an amount that is more than the amount by which innovator drug prices exceed the rate of inflation.

Roche believes that CMS should reiterate in the Final Rule that manufacturers are permitted, but not required, to make reasonable adjustments to base date AMP to address both the statutory changes (such as the exclusion of customary prompt pay discounts and the requirement to include authorized generic sales in AMP) and the upcoming regulatory changes to the AMP calculation methodology (such as changes to the definition of retail pharmacy class of trade). With respect to the change to the AMP calculation mandated by the DRA (i.e., the exclusion of prompt pay discounts), Roche recommends that CMS permit manufacturers, at their option, to adjust their pre-2007 drugs' base date AMPs by the amounts of the prompt pay discounts offered in the quarters in which their base date AMPs were established.

Additional changes to the AMP calculation that CMS may implement through its AMP regulations (e.g., a revised definition of the "retail pharmacy class of trade") could have a similar effect. Roche believes that Congress through the DRA did not intend to create artificially inflated additional rebates as a byproduct of revisions to the AMP calculation methodology. CMS should afford manufacturers the appropriate latitude in revising base date AMP to avoid the unintended consequence of erroneously inflated additional rebates.

Roche further recommends that CMS specify in its AMP regulations approaches that manufacturers may use to adjust base date AMPs to account for the effect of these changes and continue to consult with manufacturers to develop other approaches that may be preferable given their particular data management systems.

B. Reference AMP for Restatement Purposes

Roche also requests clarification on the reference AMP to be submitted during a restatement period. It is currently unclear which baseline AMP should be referenced for restatement submissions addressing a quarter prior to the DRA implementation.

C. Quarterly AMP Submissions Should Be Based on Quarterly Sales

Roche recommends that CMS clarify that quarterly AMP submissions be based on quarterly sales, not the aggregate or average of the three monthly AMPs submitted during the same quarterly period. Monthly AMP submissions are subject to volatility due to commercial customer quarterly

[14] Id. at 77185.



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payment obligations. Further, Roche recommends that smoothing for monthly AMP only, and recommends that CMS adopt the 12-month rolling average methodology that is currently applicable to ASP, beginning the period January 2007.

E. AMP and Best Price Certification

The Proposed Rule[15] requests that for manufacturer submissions (both monthly and quarterly) certification is required based on the current ASP certification guidelines. Roche proposes that the certification language be revised as applied to AMP and Best Price data submissions because the civil monetary penalty standard applicable to the reporting of ASP figures does not contain an explicit "knowing" requirement.

The Medicaid statute for civil money penalty provisions[16] states manufacturers are subject to penalty only for "knowingly" providing false information to CMS. However, the civil money penalty provision applicable to ASP submissions cites liability if a manufacturer "has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological," without specifying whether the misrepresentation was made knowingly or not.[17]

Roche proposes that the certification language include reference to the manufacturer's best knowledge at the time of submission.

## III. Additional AMP and Best Price Issues

A. Requirement of Social Security Number for AMP and Best Price Reporting

The Drug Data Reporting System (DDR) requires that the employee posting submissions on the system on behalf of a manufacturer provide his or her Social Security number. Due to the sensitive nature of a Social Security number accompanied by other personal information and the rise of identity theft, Roche respectfully recommends that access to the system include the corporation's Tax ID number (TIN) or Social Security number associated with the corporation instead of the individual's social security number.

B. Public Availability of AMP data and Federal Upper Payment Limits

Roche recommends that access to manufacturer AMP and FUL data via internet be restricted on a secure site (with password requests) only for member practitioners, providers, and

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[15] Id. at 77198

[16] SSA § 1927(b)(3)(C)

[17] 69 Fed. Reg. 17,935, 17941 (April 6, 2004).



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government agencies authorized to view such data. Open access to this information could allow competitor manufacturers to access AMP information that could lead to derived competitive intelligence on specific products and affect both commercial and Medicaid supplemental rebate offers.

* * *

We appreciate the opportunity to provide our comments and recommendations. We hope that our suggestions will assist CMS in its mission to provide Medicaid beneficiaries with access to high quality therapies. Thank you for your attention to this matter. Please feel free to contact me if you have any questions or need additional information.

Respectfully submitted,

Evan T Morris

Evan Morris
Executive Director, Federal Government Affairs and
Public Policy
Hoffmann-La Roche Inc.



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# Ahold USA, Inc.

**John J. Fegan, R.Ph.**
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February 15, 2007

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

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

On behalf of Ahold USA, we are writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Ahold operates over 650 pharmacies in 11 states. We are a major provider of pharmacy services in the communities in which our stores are located. Ahold USA is comprised of: The Stop & Shop Supermarket Company headquartered in Boston, Massachusetts; Giant Food LLC based in Landover, Maryland; Giant Food Stores LLC, based in Carlisle, Pennsylvania and Tops Markets LLC with headquarters in Buffalo, New York.

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

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

- **Define AMP to Reflect Retail Pharmacy Purchasing Costs**: CMS' proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires.

  Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of trade.

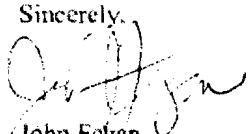
  In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating the AMP. Retail pharmacies do not benefit from these rebates and discounts, so the resulting AMP would be lower than the prices paid by retail pharmacies for medications. This proposed definition needs to be significantly modified.

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

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

We strongly support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,



John Fegan
Senior Vice President-Pharmacy Operations

**ADRIAN PRINCE**

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February 7, 2007

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

Dear Sir or Madam:

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

A proper definition of AMP is the first step towards fixing this problem.
I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained.
As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Sincerely,

Adrian Prince

Adrian Prince

February 15, 2007

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

I would like to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding: Medicaid Program: Prescription Drugs; AMP Regulation CMS 2238-P RIN 0938-AO20. I am the pharmacy manager of Caresite Pharmacy located in State College, PA. Our full service pharmacy serves a high percentage of both Medicare, PACE (PA program), and Medicaid patients. We special order supplies and deliver them along with their proscriptions. We provide free in-service programs to help with prescription issues.

1. The AMP should be just what is says.
   a) There should be an AMP for Pharmacy Benefits Managers and Mail Order Pharmacies which provide no clinical or distributed benefits to the patient. This AMP should be the Average of what these pharmacies pay for the medication, using the 11 digit NDC number.
   b) There should also be an AMP for Pharmacies that are local and provide patient information, counseling, and advice on the proscription and other medications. This AMP should be the Average of what these pharmacies pay for the medication, using the 11 digit NDC number.

2. Since there have always been attempts by varying parties, suppliers, pharmacies, insurance payers, and the pharmaceutical companies to manipulate the AWP, the MAC, or whatever, a sample review of pricing information should be conducted regularly. The sample would collect the current charge of an item based on contracts and non-contracts, and would include all discounts other than a reasonable (say 2%) timely payment discount which is customary in many industries and not a manipulation of prices. So if and item is available

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| at a list price of | $100.00 to anyone |
| and on contract for | $90.00 |
| and to Walmart for | $80.00 |
| and to BMP's and Mail Order for | $80.00 |

   then the AMP for the BMP's and Mail Order would be $80.00 and the AMP for local pharmacies would be $90.00, the average. This is because there are supply issues and often the manufacturer that you have the contract with is out and you must buy "off contract" for a higher amount. This is not unusual. Now this favors the larger chain pharmacies such as Walmart, Rite Aid, CVS, and the like, but volume contracts are a reality, and sometimes the have to order off of contract; but mail order ships it when they have it.

Thank you for consideration of these comments. I have long felt that keeping healthcare costs under control are a good idea. But when you cut costs, cut where there is excessive margins (such as with the pharmaceutical industry) not where those margins are used to provide services that are needed.

Sincerely,

Edwin Basalla-Taxis

Edwin Basalla-Taxis

MCHC
Metropolitan Chicago Healthcare Council

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February 13, 2006

TO: Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015
Submitted electronically: http://www.cms.hhs.gov/eRulemaking

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attn: Melissa Musotto
CMS-2238-P, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted by email: Paperwork@cms.hhs.gov

Office of Information and Regulatory Affairs
Office of Management and Budget
Room 10235
New Executive Office Building
Washington, DC 20503
Attn: Katherine Astrich, CMS Desk Officer, CMS-2238-P
Submitted by email: katherine_astrich@omb.eop.gov

RE: File Code: **CMS-2238-P**
Medicaid Program; Prescription Drugs
Proposed Rule published in the *Federal Register* of December 22, 2006
(71 FR 77174-77200)

I am writing on behalf of the Metropolitan Chicago Healthcare Council, which represents 140 healthcare entities, including more than 100 Illinois hospitals, the majority of which are located in the eight-county metropolitan Chicago area. We appreciate the opportunity to provide comments on the above referenced proposed rule, which implements certain provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. Our comments focus on implementation of DRA Section 6002, which prohibits federal matching funds for physician-administered drugs to Medicaid patients unless the State collects and provides utilization data for the purpose of claiming drug rebates. The proposed federal regulation pertinent to this discussion is 42 CFR 447.520.

The Centers for Medicare and Medicaid Services proposes to apply DRA Section 6002 to physician-administered drugs provided to Medicaid patients in hospital outpatient departments and clinics, and to require hospitals to report National Drug Codes (NDCs) for these services on their Medicaid claims.

Our primary concerns, which are explained in greater detail below, include:

- CMS has inappropriately applied the proposed regulation governing physician-administered drugs to services provided in hospital outpatient departments.
- CMS has grossly underestimated the cost to hospitals for reporting NDCs.
- If the proposed rule (42 CFR 447.520) is applied to hospitals, many hospitals will forego payment for eligible Medicaid services because they will not be able to comply with the NDC reporting requirements, particularly for multiple-source physician-administered drugs.
- CMS has failed to consider the impact of the proposed rule on 340B hospitals and to exempt these institutions from the NDC reporting requirements.
- State Medicaid agencies may implement more stringent requirements than outlined in the proposed federal regulation.

**We recommend that CMS specifically clarify that:**

- **DRA Section 6002 and the proposed regulation 42 CFR 447.520 do not apply to physician-administered drugs provided in hospital outpatient departments and clinics, and**
- **all hospitals, including those participating in the 340B program, are exempt from reporting NDCs on their Medicaid claims.**

## Provisions of the Proposed Regulations

CMS has inappropriately applied the proposed regulation governing physician-administered drugs to services provided in hospital outpatient departments.

- The Congressional Conference Committee Report for DRA Section 6002 underscores Congress' intent to exclude services in hospital outpatient departments. In its discussion of the collection and submission of utilization data for certain physician-administered drugs *[emphasis added]*, the Conference Committee Report (House Report 109-362) reviews current law regarding requirements for drug manufacturers to provide rebates to states for outpatient prescription drugs. It is our belief that Congress' reference to certain physician-administered drugs implies that it did not intend that all physician-administered drugs would be covered by the reporting requirements in DRA section 6002. In addition, the Report indicates that "outpatient drugs dispensed by a hospital and billed at no more than the hospital's purchasing costs are exempt from the rebate requirement," as are outpatient prescription drugs provided through managed care organizations.

- CMS makes no references to hospitals throughout its discussion of the proposed rule, and cites provisions in the Social Security Act that specifically exempt hospital outpatient services from the drug rebate program. On pages 77188-77189 of the proposed rule, CMS provides background for 42 CFR 447.520 and outlines how it expects to implement DRA Section 6002. CMS refers repeatedly to physician billing, but does not mention Medicaid claims submitted by hospitals. For example, "We expect that States will require physicians to submit all claims using NDC numbers...," and "Most States are already collecting rebates for single source drugs that are provided in a physician's office." (77189)

  The proposed regulations include a number of formal definitions for such terms as "brand name drug," "multiple source drug," and "national drug code," but there is no formal definition of "physician-administered drugs." CMS proposes on page 77188 that this latter term be defined as "covered outpatient drugs under section 1927 (k) (2) of the Act...that are typically furnished incident to a physician's service." CMS offers a number of examples of drugs that are usually injectable or intravenous and administered by a medical professional in a physician's office or other outpatient clinical setting (e.g., Lupron, epoetin alpha, and paclitaxel). It also indicates that some oral self-administered drugs such as oral anti-cancer, oral anti-emetic drugs, are included in the designation of physician-administered drugs.

  Section 1927 (k) (2) of the Social Security Act defines "covered outpatient drugs" as "those drugs which are treated as prescribed drugs for purposes of section 1905 (a) (12), a drug which may be dispensed only upon prescription..." SSA Section 1905 (a) (12), outlines the types of covered services for those eligible for medical assistance as "prescribed drugs, dentures, and prosthetic devices..." Section 1927 (k) (3) further defines what is excluded from the definition of the term "covered outpatient drug," and specifically identifies drugs that are provided "incident to or in the same setting as... outpatient hospital services."

- CMS cites a report from the Office of the Inspector General on State collection of rebates on physician-administered drugs in support of proposed regulation 42 CFR 447.520, yet this report did not examine drugs in hospital outpatient settings. On page 77188 of the proposed rule, CMS makes reference to the April 2004 OIG report, "Medicaid Rebates for Physician-Administered Drugs." In this study, the OIG found that Medicaid could have saved millions of dollars in 2001 if States had collected rebates on all physician-administered drugs, and the OIG recommended that CMS encourage States to collect rebates on these drugs. In describing the Medicaid Drug Rebate Program that was established in 1990, the OIG defines physician-administered drugs as "drugs that a medical professional administers to a patient in a physician's office." CMS later relies on the findings in this report, which excludes hospital services, in estimating state and federal savings from implementation of DRA Section 6002 (see Regulatory Impact Analysis below).

**Collection of Information Requirements**

CMS has grossly underestimated the cost to hospitals for reporting National Drug Codes (NCDs).

- Individual hospital costs to provide NDCs exceed CMS' national estimate for all providers. The proposed regulation 42 CFR 447.520 requires providers, beginning January 1, 2007 to submit Medicaid claims for physician-administered single-source drugs and the 20 highest dollar multiple-source drugs using NDCs. On page 77189 of the proposed rule, CMS makes reference to hospital outpatient departments when it indicates that the burden associated with this requirement is the time and effort to place an NDC on a Medicaid claim. CMS anticipates that the NDC reporting requirements will affect more than 20,000 physicians, hospital outpatient departments, and other entities that together submit more than 3.9 million Medicaid claims annually. CMS estimates the cost of nine cents ($0.09) per claim to provide the NDC. Nationally this equates to a total estimated annual cost to all physicians and hospitals of only $344,000 – an amount that is less than some of the estimates individual hospitals believe it will take to make the necessary changes to integrate their separate pharmacy and billing systems and to capture the NDCs for billing purposes. Although most hospitals cannot determine the specific cost of providing NDCs on their claims, estimates range as high as $5 million to create the automated systems to do so, with ultimate outlays depending on the vendors individual hospitals use for their internal systems. Costs to develop a manual process to provide the NDCs are estimated minimally at $10 per claim.

- The proposed NDC billing requirement is unique to Medicaid claims and is a HIPAA data standard previously rejected by CMS for institutional providers. No other government agency or third-party payer requires hospitals to report NDCs for drugs administered in an outpatient setting, so any internal systems change to provide NDCs would be made solely to accommodate the Medicaid program. In fact, when adopting standards for the eight different electronic transactions required under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), CMS ultimately repealed NDCs as the standard medical data code set for reporting drugs and biologicals on institutional and professional claims, while allowing NDCs to remain the standard medical data code set for reporting drugs and biologicals for retail pharmacy claims. In making this decision, CMS was influenced by testimony from the healthcare industry that the NDC should not be used on professional and institutional claims, including concerns that the cost of converting to the NDC was high and would not justify the benefits.

- If the proposed rule (42 CFR 447.520) is applied to hospitals, many hospitals will forego payment for eligible Medicaid services because they will not be able to comply with the NDC reporting requirements, particularly for multiple-source physician-administered drugs. Reporting NDCs for hospital outpatient services poses significant challenges to hospitals since many pharmacy departments do not capture the NDC or use it in inventory or dispensing. In addition, the pharmacy's internal systems are not tied to the hospital's billing and medical record systems, and the various systems may be supported by different vendors, thus precluding the interfaces required for NDC reporting. In a hospital setting, the physician generally orders drugs for a patient by name, unit, dosage, and frequency. The order is filled by the hospital's pharmacy, and a charge based on dosage initiated for the service, all without referencing the NDC.

  While some hospitals may be able to tie the NDC to the HCPCS code in their charge description masters, or may be able to do this through an interface between the pharmacy and billing systems, providing the correct quantity for the NDC (which may differ from the quantity for the J-code) may be problematic. This is particularly true for multi-dose packaged drugs that the hospital pharmacy repackages into single-doses, such as for the oral self-administered drugs CMS anticipates being covered by the

proposed 42 CFR 447.520. What is a meaningful quantity for a single-dose of a drug that is originally packaged by the manufacturer in multiple doses with one NDC? Tying the NDC to the HCPCS code in the hospital's charge description master is not possible for accurately reporting multiple-source drugs, which by definition have multiple NDCs that crosswalk to a single HCPCS code. In addition, pharmacy systems may not be able to accommodate separate profiles for each manufacturer from which the same drugs are purchased.

Despite their opposition to reporting NDCs to Medicaid, MCHC member hospitals have been working with their vendors to determine how and whether this reporting is possible since the State has already communicated its intent to require NDCs for physician-administered drugs (see comments below under Other Critical Concerns). While some hospitals have determined how to do this for single-source drugs, and admittedly a small number have already begun to include NDCs for single-source physician-administered drugs on their Medicaid claims, other hospitals have examined their systems and do not anticipate that they will ever be able to report NDCs for single-source drugs. Many more hospitals have examined their systems and have determined that they do not expect to ever be able to accurately report NDCs for multiple-source drugs.

**Regulatory Impact Analysis**

The cost for hospitals to implement systems to support NDC reporting exceeds estimated savings for using this information to obtain drug rebates on Medicaid patients. On page 77190, CMS estimates that rebates on physician-administered drugs for implementation of DRA Section 6002 will save the federal government $18 million and all state governments $13 million in 2007. Total savings for a five-year period (2007-2011) are estimated at $179 million. These estimates are based on the 2004 OIG report, "Medicaid Rebates for Physician-administered Drugs." As noted above, this report, and hence the estimates in the proposed rule, do not include any physician-administered drugs provided in hospital outpatient departments. Please refer to our comments on Collection of Information Requirements above. When applied across all hospitals, the estimated costs of compliance for individual hospitals to implement systems upgrades to permit automated NDC reporting far exceeds the savings that CMS predicts will accrue from implementing DRA section 6002.

On page 77193 of the proposed rule, CMS believes the cost to a hospital for manually adding the NDC to a claim "would be minimal," and it acknowledges that "we are not able to estimate the cost to make this [one-time systems] change." The proposed rule references the fact that some State Medicaid agencies have already required the reporting of NDCs for physician-administered drugs, and more are expected to do so in the absence of the DRA Section 6002. Again, please refer to our comments in the previous section. The cost for hospitals to report NDCs is not minimal, and accurately reporting NDCs for multiple-source drugs may not be possible at all.

Certainly one of the more important concerns hospital pharmacies have is being required to develop a system that is unique to Medicaid patients when the pharmacy does not operate on a day-to-day basis based on the financial class of the patients requiring their services. Whether the patient is covered by Medicaid is not a factor when dispensing drugs in a hospital setting.

**Other Critical Concerns**

- CMS has failed to consider the impact of the proposed rule on 340B hospitals and to exempt these institutions from the NDC reporting requirements. Section 340B of the Public Health Service Act requires drug manufacturers to provide discounts on purchases of outpatient drugs by covered entities that are admitted into the program. Drugs purchased under the 340B program cannot also be eligible for rebates under the Medicaid drug rebate program. Since discounts have already been given for outpatient drugs purchased by hospitals participating in the 340B program, state Medicaid agencies cannot also apply for rebates. As a result, these hospitals should not be expected to report physician-administered drugs using NDCs. This issue is of particular concern since 340B hospitals by definition treat a high volume of Medicaid and low-income patients and are not in the financial position to incur unnecessary administrative expenses – resources that are better spent actually providing care to the disadvantaged in their communities.

- In the absence of a CMS clarification that the proposed regulation 42 CFR 447.520 does not apply to hospital outpatient services and that hospitals are not required to report NDCs on their claims, State Medicaid agencies may implement more stringent requirements than outlined in the proposed federal regulation. CMS has already issued State Medicaid Director letters that urge States to require NDC reporting for the collection of drug rebates. In Illinois, the Medicaid agency has responded to CMS' instructions by issuing provider communications regarding its plans to require NDCs for physician-administered drugs furnished in hospital outpatient settings. Although this requirement was announced in 2005, programming the related Medicaid claim adjudication edits is just now being finalized by the State.

  We have learned that effective for Medicaid claims submitted on or after July 1, 2007, charges for physician-administered drugs on hospital outpatient claims will be denied if the NDCs are not provided. This applies to all single-source drugs and to all multiple-source physician-administered drugs (not just the top 20 identified by CMS as specified in DRA Section 6002). It also applies to all Medicare crossover claims for dually eligible patients even though NDCs are not required by Medicare, the primary payer. In addition, all physician-administered drugs provided by 340B hospitals must be billed with NDCs in order to be paid, even though drugs purchased at a discount are not eligible for rebates.

  In Illinois, hospitals will be required to report two service lines for both the HCPCS code (J-code) and a quantity that relates to the HCPCS description for the code, as well as the related NDC and the quantity associated with the NDC for each physician-administered drug. It is important to emphasize that our Medicaid agency will continue to use the HCPCS code to determine payment for physician-administered drugs, yet payment for the drug charges will be denied if NDCs are not reported; the NDC is required solely for claiming eligible drug rebates.

**Recommendations**

**We recommend that CMS specifically clarify that:**

- **DRA Section 6002 and the proposed regulation 42 CFR 447.520 do not apply to physician-administered drugs provided in hospital outpatient departments and clinics, and**

- **all hospitals, including those participating in the 340B program, are exempt from reporting NDCs on their Medicaid claims.**

**Further Information**

Thank you again for the opportunity to review CMS' proposal and to offer comments. If you have any questions about the issues raised above or if you need any additional information, please feel free to contact me at 312/906-6007, email smelczer@mchc.com.

Sincerely,

Susan W. Melczer

Susan W. Melczer
Director, Patient Financial Services

cc: American Hospital Association
Illinois Hospital Association

## CMS Paperwork

**From:** Susan Melczer [SMELCZER@mchc.com]
**Sent:** Thursday, February 15, 2007 11:04 AM
**To:** CMS Paperwork
**Subject:** CMS-2238-P
**Attachments:** NDC-021307-CMS comment letter.pdf

Please find attached comments on the above referenced proposed rule:
<<NDC-021307-CMS comment letter.pdf>>

Susan W. Melczer
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THE UNIVERSITY OF TEXAS
# HEALTH CENTER
AT TYLER

Department of Pharmacy

February 5, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

On behalf of The University of Texas Health Center at Tyler, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. The University of Texas Health Center at Tyler is a 115 bed hospital located in Tyler, Texas, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. Hospital billing systems are not created to pull this data to a bill. To accommodate, our facility would be required to pay for custom programming from our software vendors. In addition, this would require an additional FTE in the pharmacy department to facilitate continuously updated NDC files in the Pharmacy software. It is not feasible to ask that hospitals attempt to manually add these NDC numbers to a bill. As contracts change quarterly, hundreds of drug NDC #s would need to be modified to ensure integrity in reported data. An estimate of financial ramification to our facility would be over $60,000 per year not including custom programming cost estimated over $30,000. This doesn't even take into consideration a facility having more than one brand of generic being used at the same time in different areas of the facility due to inventory changes.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. It has long been understood in the hospital community that hospital clinic administered drugs are exempt from rebate requirements under the Medicaid stature. Yet the express purpose

THE UNIVERSITY OF TEXAS
HEALTH CENTER
AT TYLER

Department of Pharmacy

of the NDC collection rule for "physician administered drugs" is to facilitate rebate collections by the States. The new rule proposed by CMS to implement Section 6002 of the DRA should take this pre-existing statutory exemption from rebates into account, and similarly except hospital outpatient clinic drugs from the new NDC collection rule. It makes no sense to require the states to collect NDC information so that they can more easily collect rebates on drugs that are exempt from rebates in the first place. Many of these medications are extremely expensive. If all cost savings are passed through to the Medicaid program, it leaves hospitals moving very expensive medications for small fees. This in addition to increased administrative burden and costs bring up a strong debate within our hospital on whether it is worth participating in the 340B program.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. CMS should clarify that the new formula for AMP computation is not applicable in calculating 340B ceiling prices, because the 340B statute expressly provides for continuing to utilize the statutory definition of AMP that existed prior to enactment of the DRA. Driving up 340B costs will have a negative ramification across our facility.

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

Sincerely,

Melissa Maeker RPh

Melissa Maeker R.Ph.
Director of Pharmacy
The University of Texas Health Center at Tyler
Tyler, Texas



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NOVARTIS

David P. Tolman
Sr. Vice President &
General Counsel
OTC Global Head Legal

Novartis Consumer Health, Inc.
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T: 973 503 7661
F: 973 503 8440

February 19, 2007

*Sent via FedEx Delivery*

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

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

Dear Administrator Norwalk:

I am pleased to submit the following comments on behalf of Novartis Consumer Health, Inc. (NCH), regarding the above-referenced rule (the Proposed Rule).[1] NCH is a world leader in the development, production and marketing of self-medication products for the in-home treatment and prevention of medical conditions and ailments and to enhance overall health and well being. Our portfolio of over-the-counter (OTC) products includes topical analgesics, athlete's foot treatments and nasal decongestants. In addition, NCH manufactures a limited number of prescription medications, including products for the treatment of cold sores and motion sickness.

NCH appreciates the valuable guidance that the Centers for Medicare & Medicaid Services (CMS) has provided in the Proposed Rule regarding the calculation of average manufacturer price (AMP) and Best Price. NCH thanks you for the agency's willingness to work with manufacturers to bring clarity to these pricing calculations. We write, however, to highlight two areas where we believe there is continued uncertainty for manufacturers of consumer health products and to ask for additional clarification in the Final Rule.

## I. NCH Asks that CMS Clarify that, in the Consumer Health context, the Primary Manufacturer Includes the Sales of Authorized Generics to the Secondary Manufacturer in its AMP and Best Price Determinations, not the Sales to Consumers by the Secondary Manufacturer.

The Proposed Rule implements changes made to the Medicaid Drug Rebate statute by the Deficit Reduction Act regarding authorized generics. Specifically, the Proposed Rule requires the manufacturer holding title to the original National Drug Application (NDA) include the sales of the authorized generic in the AMP and Best Price calculations for the branded drug.[2] In discussing this

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

2 *Id.* at 77,198 (proposed 42 C.F.R. § 447.506).

requirement in the preamble to the Proposed Rule, CMS directs that "the sales of authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs" be included in the AMP and Best Price calculations of the branded product.[3] This approach is appropriate in the context of *prescription* authorized generic products, because the secondary manufacturer does not sell the product directly to the public but rather to other entities, such as health care providers and retailers, and the AMP and Best Price calculations are intended to measure sales transactions with those entity types. In the context of consumer health OTC products, however, the branded manufacturer typically sells the authorized generic to the secondary manufacturer, such as grocery stores and retail pharmacies, at commercial pricing and those entities sell the authorized generic product directly to consumers. NCH requests that CMS clarify, therefore, that in the consumer health and OTC context, the authorized generic sales included in the AMP and Best Brice determinations for the branded drug are the primary manufacturer's sales of the authorized generic to the secondary manufacturer.

The consumer health industry maintains a competitive market for the sale of authorized generics to grocery stores, drug stores, and other retailers. Consumer health product manufacturers negotiate with these retailers for the opportunity to produce and market generic versions of their branded drugs under the retailer's name, *i.e.*, store brand. The branded or primary manufacturers' sales of the store brand products to retailers are at commercial prices and are not subject to transfer pricing or other such profit-sharing arrangements. In many cases, the primary manufacturer agrees to label the store brand products under the retailer's labeler code, making the retailer a secondary manufacturer of those drugs.[4] Unlike secondary manufacturers of *prescription* authorized generic products, which sell their authorized generics to other entities such as health care providers and retail pharmacies, a retailer/secondary manufacturer of an *OTC* authorized generic sells the authorized generic directly to consumers. Such retailers also typically do not participate in the Medicaid Drug Rebate Program.

In these circumstances, the sales data for the authorized generic that are most appropriate to include in the branded product's AMP and Best Price calculations are the primary manufacturer's sales transactions with the retailer. First, direct and indirect sales to retailers are the type of sales transactions that the primary manufacturer includes in its own calculation of the branded product's individual, non-blended, AMP and Best Price, and so, in deriving the blended AMP and Best Price figures inclusive of the authorized generic's sales, the primary manufacturer should incorporate the same type of sales transactions, *i.e.*, the direct and indirect sales to retailers of the authorized generic. This approach is consistent with CMS' guidance in the preamble, quoted above, which would direct the blending of sales transactions to like entities, *i.e.* the primary and secondary manufacturer's direct and indirect sales to health care providers and retailers. Second, this approach is achievable within the data limitations in the consumer health industry. Unlike the AMP and Best Price data available from secondary manufacturers of prescription drugs, neither AMP and Best Price data nor transaction data for secondary manufacturers' sales of store brand OTC products to consumers are made available to primary manufacturers. Third, this approach also complies with the language of

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[3] *Id.* at 77,184.

[4] The authorized generic also could be labeled with the primary manufacturer's labeler code but with a different product code portion of the National Drug Code (NDC). In this case, there would be no secondary manufacturer and the primary manufacturer would blend its own sales data for the branded and authorized generic products.

the proposed regulation, which directs, in the case of AMP, that the primary manufacturer "include the direct and indirect sales" of the authorized generic in the branded product calculations, and as to Best Price, "include the price of [the authorized generic]"in the branded product's Best Price calculation.[5] The proposed regulatory language does not distinguish between sales by the primary and secondary manufacturer. CMS did so only in the preamble discussion of this requirement.

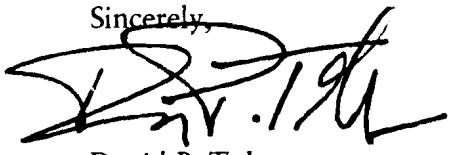
For all of these reasons, we urge CMS to clarify that in the case of consumer health OTC products, a primary manufacturer may comply with the DRA and the Proposed Rule by including its sales of the authorized generic to the secondary manufacturer when the primary manufacturer calculates of the blended AMP and Best Price figures for the branded product.

## II. NCH Asks CMS to Clarify that Drugs Sold Through Company Stores Are Not Included in AMP or Best Price

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

We thank CMS in advance for its serious consideration of these comments and look forward to working with you to ensure accurate Medicaid price reporting. Please feel free to contact me at 973-503-7661 if you have any questions regarding our comments or need additional information.

Sincerely,



David P. Tolman
General Counsel
Novartis Consumer Health, Inc.

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5 *Id.* at 77,198 (proposed 42 C.F.R. § 447.506).

6 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. § § 447.504(g)(7) (AMP) and 447.505(c)(7) (Best Price).

7 71 Fed. Reg. at 77,196 (emphasis added).

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

Centers for Medicare & Medicaid Services
Proposed Rule CMS-2238-P

Submitter:
Marijo G. Bustos
Abraxis BioScience, Inc.
1501 East Woodfield Road, Suite 300 East
Schaumburg, IL 60056
February 20, 2007

Background:

1. Please provide clarification on the release of AMP to states. How will the relationship between the AMP and the unit of measure be determined? Confusion is possible between the unit of measure used for AMP and the unit of measure most familiar to providers and patients.
2. How will prompt pay and nominal price sales be reported?
3. Please help clarify authorized generics. What relationship do drug sales have to this relationship? If product is sold from one manufacturer to another, are the manufacturers required to calculate data based on both labeler codes?
4. How will conflicting roles of AMP be balanced? Lower AMP may allow lower rebate payments by manufacturers, but might lead to pharmacies not receiving sufficient reimbursement. Higher AMP may allow pharmacies to receive higher payment, but might not best reflect all pricing in the market.

Provisions of the Proposed Regulations:

1. How is legal title of NDC being defined? If product is sold from one manufacturer to another, are the manufacturers required to calculate data based on both labeler codes?
2. The FDA maintains the 10-digit number code. What impact does this have to the reference of 11-digit numerical code referenced in the proposed rule?
3. Two unique purposes for AMP are discussed (rebate liability and payments). The AMP also serves the purpose of providing a ceiling price for the 340B program. What considerations are being given to the 340B program and the impact of the changes to AMP?
4. Posting of AMP on a public website may cause confusion to the general public. Many products have AMP values at a different level than found in pharmacies. What is planned to prevent the confusion possible with different unit of measures?
5. Mail order services should be considered as retail class of trade. This is consistent with definitions of retail class of trade being facilities that distribute to the general public.
6. Difficulties in obtaining details related to PBM contracts suggest that the data should be excluded from Medicaid calculations. Data is very difficult to confirm from an operational perspective. Additionally, the difficulties could lead to differing interpretations and potential compliance issues.
7. Is the definition of AMP being changed? Is AMP the price received by the manufacturer? Is AMP the price recognized by the manufacturer? Is AMP the price paid by the retail class of trade?
8. Please clarify function of customary prompt pay in relation to BP.

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February 20, 2007

9. The phrase "prices which are actually available" is used in the proposed rule. Available price should not be used to define AMP. If a price is offered and not taken it is irrelevant to price received by manufacturers or price paid by retail pharmacies. Please clarify this language.
10. Monthly AMP figures will be prone to fluctuation due to the lagged data received for chargebacks and rebates. A 12 month rolling average for all lagged data would help to provide a consistent value from month to month.
11. Since the definition for AMP is the same for monthly and quarterly calculations a 12 month rolling average for lagged data should be used for quarterly calculations. Multiple calculation methods are difficult to track and maintain. Methodology for monthly and quarterly calculations should be consistent which is only possible if both monthly and quarterly include rolling averages.
12. Will data released to the public be at the 11-digit numerical code level? How will AMP at 9-digit numerical code level be used to provide 11-digit number code level information?
13. How will company certification be accomplished? Since the proposal is to submit data via the internet, how will certification be completed? Will it be under separate cover? Will it be an attachment to the internet site?
14. How will nominal sales be reported? What format will be used?
15. Interaction with providers indicates that not all generic or brand name drugs have a HCPCS code assignment. If HCPCS codes will be necessary what will be done to provide codes for drugs without a code assignment?

Collection of Information Requirements:
The regulation will require manufacturers to report data 16 times a year rather than 4 times a year. This is a significant burden in resources and data retention. Although the process is the same, the fact that it must be completed 12 additional times each year will be very demanding from an operational perspective. This is especially true for smaller manufacturers.

Regulatory Impact

1. The collection method has not been finalized. It appears that it will be an internet based system, requiring manual entry by a user. Again, a requirement to complete this task manually, 16 times a year will have major impact to manufacturers, especially the smaller manufacturers.
2. New data requirements for prompt pay and nominal pricing will also result in major impact. How will the data be reported?

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February 20, 2007

3. There is a large difference between capturing data from a system to calculate and capturing data to report. This too will have major impact to manufacturers.
4. Collection of information by the manufacturer will be further complicated due to requirements by other programs. The 340B program is directly impacted by the proposed rule. Without changes to the proposed rule it is likely that the 340B program will require another calculation which will further strain manufacturer resources.
5. There is an assumption that system changes would be low impact. Something that appears to be a simple change often results in very complex system changes. Please think of system changes necessary to allow for the year 2000. This would appear to be a simple change but was not.
6. The estimated cost to manufacturers will be included in business operations and result in higher drug prices.
7. Economic impact estimates do not include potential costs that will impact the 340B program and manufacturers to meet 340B program requirements.
8. The definition for monthly and quarterly AMP is defined as the same. Different calculations for monthly and quarterly AMP are inconsistent with the definition. An averaging should be used for both.
9. Are there federal rules for the 340B program? If yes, there is clear overlap of requirements.

Definitions:

1. Sales to hospitals defined as use by the outpatient pharmacy is a change to previous guidance. This will be very difficult to confirm and track. Many facilities separate stock within their organizations and manufacturers will be unaware which sales are inpatient and which are outpatient. Hospital sales should not specify inpatient/outpatient. All hospital sales should be excluded from AMP.
2. Further clarification of data certification is necessary.

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# Planned Parenthood of Connecticut, Inc.



February 16, 2007
Ms. Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the Chief Operating Officer of Planned Parenthood of Connecticut, Inc. (PPC), a non-profit health care provider that operates 19 health centers throughout the state. Thirteen of our centers receive Title X funding, 11 participate in the CDC-funded Infertility Prevention Project. One of our centers, located in Enfield, is not funded by either program and therefore is not eligible for the 340 B program and discounted drug prices.

While it does not receive federal funds, PPC's Enfield center is just as commited to serving uninsured, low income women as PPC's other centers. Of the 1,900 women and men PPC-Enfield serves each year, more than half are uninsured. Of those, 26% report a family income at or below 100% of the federal poverty guideline; 80% report a family income at or below 150% of the federal poverty guideline. As is the case for all PPC health centers, patients at our Enfield center are charged according to an income based sliding fee scale, and no one is turned away because they can't afford to pay.

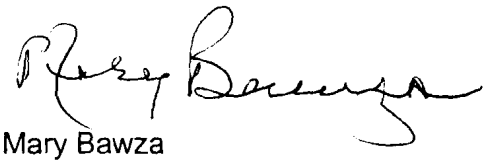
Yet, it is becoming increasingly hard to maintain these discounted fees and policy of turning no one away without having access to discounted drug prices. PPC has been able to serve women in need in Enfield and throughout the state because we have been able to purchase oral contraceptives and other drugs from manufacturers willing to offer them at nominal prices. If we continue to have to purchase contraceptives and other drugs at the higher prices for our Enfield center, we will have to either raise prices for our self pay patients, limit Enfield's hours and/or services, or be forced to close the center altogether.

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned and operated nursing homes. Even though PPC's Enfield center is not covered by the 340B program, it nonetheless serves as a safety net provider for its community. Our ability to continue to do so rests on our

ability to purchase contraceptive drugs at a nominal price. For this reason, we are deeply disappointed that CMS did not define "safety net provider" or apply the ability to purchase nominally-priced drugs to other safety net providers in the proposed rule.

We sincerely hope that the Centers for Medicare and Medicaid (CMS) will reconsider and exercise it's authority to name "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. PPC's Enfield Center is clearly a safety net provider and we strongly urge CMS to include in its definition of safety net proivders, non-profit, outpatient clinics like ours.

Respectfully submitted by,



Mary Bawza
Chief Operating Officer
Planned Parenthood of Connecticut, Inc.

# KAW NATION

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(580) 269-2552 Fax (580) 269-1157


February 14, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
CMS/DHHS
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

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

Dear Ms. Norwalk,

As Chairman of Kaw Nation, I would like to thank you for this opportunity to provide comments to the proposed regulations, published in the Federal Register on December 22, 2006, at Vol. 71, No. 246, implementing provisions of the Deficit Reduction Act (DRA) pertaining to prescription drugs under the Medicaid program. It is imperative that the States consult with American Indians and Alaska Natives (AI/AN) concerning any amendments to the DRA in their state plans.

This proposed rule will limit State Medicaid expenditures for certain multiple source drugs. Indian Health Service (IHS) and tribal programs depend on the Medicaid reimbursements to supplement existing IHS appropriations sustaining tribal programs, which are continually under funded. Many of these pharmacies are small and operate in remote rural areas. Any changes in Medicaid reimbursements can have a negative effect on their financial sustainability. Without consultation, implementation of this rule may have unintended negative consequences on Indian health programs.

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

Consistent with CMS policy, we are requesting that CMS insert language in the final rule that would require States to consult with Tribes in the development of any State plan amendment; which would modify existing payment methodologies for prescription drug reimbursements.

This will allow each Tribe the opportunity to work with their State to assess local impacts prior to submission of State Plan amendments.

We are also requesting that CMS insert language in the final rule to encourage States to maintain their current level/type of reimbursement and filling fees to Tribal and IHS pharmacies. Tribal and IHS providers should be explicitly recognized as essential safety net pharmacies.

Thank you again for your continued support on this and other issues affecting Indian Country. If you should have any questions please contact me at (580)269-2552.

Sincerely,

Guy Munroe, Chairman / CEO
Kaw Nation

GM/tlw

52

Mer-Rob Your Rx 1st Choice

PHARMACY

Owner, Ronald L. Pate, Pharm. D.

2112 Helton Drive
Florence, Alabama 35630

Phone (256) 764-4474
Fax (256) 764-3720

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

2/15/2007

To Whom It May Concern:

I have informed my staff that on July 1, 2007 that we will no longer service Medicaid recipients. The proposed rule for AMP as described by the Deficit Reduction Act, pertaining to the Medicaid program, will result in reimbursement of 36% below acquisition cost. I am sending a copy of this letter to all Congressmen and Senators from Alabama. Please reconsider and prevent this disaster.

Thanks,

Ronald L. Pate BSSc, BPharm, PharmD

53

FOSTER DRUG OF AL, INC.
115 NORTH MEMORIAL DR.
PRATTVILLE, AL 36067 (334)365-3327

February 14, 2007

CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPT. OF HEALTH & HUMAN SERVICES
BALTIMORE, MARYLAND 21244-1850

TO WHOM IT MAY CONCERN;

The purpose of this letter is to express our strong opposition to CMS's plan to implement "AMF" pricing for federal reimbursement of Medicaid generic prescriptions. As an independent retail pharmacy, we would lose drastically on any prescriptions filled for generics under a state Medicaid program. Pharmacies like ours stand to lose 36% or more on each generic Medicaid prescription we fill under this act.

The independent pharmacies have always been an integral part of community healthcare and yet are continuously being squeezed by the drug manufactures, PBM's ,mail order pharmacies and government agencies. Ultimately,drugstores will have to close their doors and the health and welfare of the communities we serve will suffer.

We respectfully and earnestly ask that the proposed rule under the Deficit Reduction Act pertaining to the Medicaid programs not be implemented. The future livelihood of our business and countless others like us along with the health and welfare of our communities is at risk if this act is put into effect.

Sincerely,

Garry B. Meinsler, RPh.

Garry B. Meinsler R.Ph.

52-1

FOSTER DRUG OF AL, INC.
115 NORTH MEMORIAL DR.
PRATTVILLE, AL 36067 (334) 365-3327

February 14, 2007

CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPT. OF HEALTH & HUMAN SERVICES
BALTIMORE, MARYLAND 21244-1850

TO WHOM IT MAY CONCERN;

The purpose of this letter is to express our strong opposition to CMS's plan to implement "AMF" pricing for federal reimbursement of Medicaid generic prescriptions. As an independent retail pharmacy, we would lose drastically on any prescriptions filled for generics under a state Medicaid program. Pharmacies like ours stand to lose 36% or more on each generic Medicaid prescription we fill under this act.

The independent pharmacies have always been an integral part of community healthcare and yet are continuously being squeezed by the drug manufactures, PBM's ,mail order pharmacies and government agencies. Ultimately,drugstores will have to close their doors and the health and welfare of the communities we serve will suffer.

We respectfully and earnestly ask that the proposed rule under the Deficit Reduction Act pertaining to the Medicaid programs not be implemented. The future livelihood of our business and countless others like us along with the health and welfare of our communities is at risk if this act is put into effect.

Sincerely,

Henry C.Foster, Jr. R Ph..

THE PHARMACY AT WAL-MART®

Bob Dufour, R.Ph
Director, Pharmacy Professional Services/Government Relations
702 S.W. 8th Street
Bentonville, AR 72716-0230
(479) 273-4071 – office
(479) 277-9679 – fax
bob.dufour@wal-mart.com

February 20, 2007

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

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

This letter is to provide comments on the proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Wal-Mart is a major provider of Medicaid prescriptions. Significant savings to the Medicaid program are achieved with our every day low prices and $4 generic prescription program. We operate over 3,900 pharmacies in 49 states and Puerto Rico, including a mail order pharmacy and a specialty pharmacy.

As CMS reviews comments on the proposed regulation, we would ask your consideration of the following:

- **Timing of implementing FUL's for generic drugs:**
  CMS is required to promulgate a regulation by July 1, 2007 to clarify the AMP calculation. Implementing new FUL's based on AMP should occur only after manufacturers have reported in accordance with regulations implemented by CMS for AMP.

- **Defining AMP to reflect price paid by "retail pharmacy class of trade" for Program drugs:**
  "Retail class of trade" is not universally defined. Variation may exist in the marketplace among manufacturers as to class of trade PBM's and mail order pharmacies belong. AMP's used to determine Federal Upper Limits should reflect those prices at which retail pharmacies may purchase drugs for the **program**.

  CMS should take into consideration how price concessions are earned by Mail order and PBM's. Mail order and PBM's pharmacies are able to provide manufacturers with increased market share via use of formularies and incentives, such as co-payments. In return for increased market share and profits, manufacturers share these monies with mail order and

PBM pharmacies. These monies and incentives are not available to mail order and PBM's for Medicaid prescriptions. Medicaid requires manufacturers to pay rebates/incentives directly to States. Manufactures expressly exclude Medicaid prescriptions from incentive programs offered to PBM's and mail order. Calculation of AMP for the purpose of establishing FUL's should exclude discounts or incentives that are not available for Medicaid prescriptions.

- **Adequate supply criteria:** CMS also proposes FUL's to calculate using the least costly therapeutic equivalent. This criterion should be changed to include adequate availability of supply.

- **Public Release of AMP:** The Centers for Medicare and Medicaid Services (CMS) should carefully consider if making each manufacturer's AMP publicly available will eliminate generic competition and result in higher pricing of generics for the Medicaid program. Under this scenario the following could occur:
  1. As manufacturers' AMPs are published, those pharmacies purchasing above the average will demand pricing at or below the AMP. This effect will result in downward pressure on pricing. Each time a manufacturer has their Average Manufacturer Price published (if the manufacturer sold to different purchasers for different prices); there will be those purchasers who paid above the AMP. Purchasers paying above AMP will continue to demand the AMP until a manufacturer determines that all purchasers will have one price, at which point no purchaser is paying above the AMP.
  2. With AMP prices publicly available, expect the commercial market to migrate from AWP reimbursement to AMP based reimbursement.
  3. Today, pharmacy purchasers negotiate with manufacturers and wholesalers for generic pricing. Under AMP, expect a compression of discounts available and movement towards a unitary price.
  4. With the diminished negotiating power of purchases, generic manufacturers would have reduced pressure on pricing, allowing them more ability to inflate pricing of generic drugs. The net effect, therefore, would be an ultimate increase in generic drug prices.

  CMS should consider if the Medicaid program would be better served by not making AMPs publicly available, if, in fact, this would result in decreased competition and higher prices.

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

Sincerely,

Bob Dufour

>>>
>>>
>>>Ms. Norwalk,
>>>
>>>
>>>
>>>The purpose of this letter is to comment on the proposed rule
>>>(CMS-2238-P) regarding the reimbursement of pharmacy providers based
>>>on the AMP model
>>as
>>>set forth in the Deficit Reduction Act of 2005.
>>>
>>>
>>>
>>>As I am sure you are well aware, pharmacy services are an integral
>>>part of the health care of all Americans, but especially
>important to
>>>the health care of the poor, indigent, or others who qualify
>for state
>>>Medicaid assistance. This population may be at an increased risk of
>>>poor health care due to various influences, and often, pharmacy
>>>services, such as prescriptions, may be on of the most efficient and
>>>influential accesses
>>for
>>>the recipient.
>>>
>>>
>>>
>>>Unfortunately, quality health care does come with a cost, and the
>>>pharmacy piece is no different. If CMS-2238-P is implemented in its
>>>current form, my pharmacy will be reimbursed below the cost of
>>>acquisition for the medication. This does not consider the recently
>>>released report from the accounting firm Grant Thornton LLP National
>>>Study to Determine the Cost of Dispensing Prescriptions in Community
>>>Retail Pharmacies in which it is reported that the median cost of
>>>dispensing a prescription for a pharmacy is $10.51.
>>>
>>>
>>>
>>>My concerns are further supported by the GAO's report that
>states that
>>>community pharmacies, such as mine, will lose an average of 36% on
>>>each generic prescription filled for Medicaid recipients.
>My pharmacy
>>>will not be able to fill Medicaid prescriptions under such
>an environment.
>>>
>>>
>>>
>>>Pharmacists save money for state Medicaid agencies, CMS, and
>this country.
>>>If the AMP is not defined fairly, from a retail pharmacy
>perspective,
>>>and if the GAO report is accurate, many pharmacies, including my
>>>pharmacy,
>>will
>>>be unable to fill Medicaid prescriptions or will cease to
>exist. This
>>>in turn will decrease access for the Medicaid recipient and will
>>>increase the costs for Medicaid and this country far above
>any savings
>>>that are to be realized through AMP pricing for generic
>prescriptions.
>>>
>>>
>>>
>>>Sincerely,

>>>
>>>
>>>
>>>Greg Moorer, RPh
>>>
>>>Owner, Oak Ridge Pharmacy
>>>
>>>
>
>

## Teeters, Margaret A. (CMS/OSORA)

**From:** Lafferty, Tiffany R. (CMS/OSORA)
**Sent:** Wednesday, February 07, 2007 1:48 PM
**To:** Simon, Carlos (CMS/OSORA); Teeters, Margaret A. (CMS/OSORA); Hayes, Yolanda K. (CMS/OSORA)
**Subject:** FW: Pharmacy reimbursement base on AMP Model

>-----Original Message-----
>From: Gurule, Roman (CMS/OSORA)
>Sent: Wednesday, February 07, 2007 1:46 PM
>To: Shortt, Michelle R. (CMS/OSORA); Lafferty, Tiffany R. (CMS/OSORA)
>Subject: FW: Pharmacy reimbursement base on AMP Model
>
>Please see below comments. Thank you.
>
>>-----Original Message-----
>>From: Hough, Stephanie F. (CMS/OA)
>>Sent: Wednesday, February 07, 2007 1:39 PM
>>To: Gurule, Roman (CMS/OSORA)
>>Subject: FW: Pharmacy reimbursement base on AMP Model
>>
>>Roman, can you please include this for AMP comments/feedback? Thanks!
>>
>>>-----Original Message-----
>>>From: Greg Moorer <dgmoorer@comcast.net>
>>>To: Norwalk, Leslie V. (CMS)
>>>Sent: Tue Feb 06 13:01:34 2007
>>>Subject: Pharmacy reimbursement base on AMP Model
>>>
>>>OAK RIDGE PHARMACY
>>>
>>>4180-A OAK RIDGE AVE
>>>
>>>MOBILE, AL 36619
>>>
>>>PH (251) 666-0891
>>>
>>>FAX (251) 661-0483
>>>
>>>
>>>
>>>
>>>
>>>February 6, 2007
>>>
>>>
>>>
>>>Leslie Norwalk
>>>
>>>Acting Administrator
>>>
>>>Centers for Medicare and Medicaid Services
>>>
>>>Department of Health and Human Services
>>>
>>>Attention: CMS-2238-P
>>>
>>>P.O. Box 8015
>>>
>>>Baltimore, MD 21244-8015
>>>

The Drug Store Pharmacy, Inc.
2940 Groveport Road
Columbus, Ohio 43207
614-491-3446

February 7, 2007

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

Dear Ms. Norwalk,

The proposed regulation (CMS-2238P) to reimburse pharmacies for generic prescriptions using AMP will have a devastating effect on all retail pharmacies that dispense prescriptions to Medicaid patients. It should be understood that instituting AMP as the basis of actual cost to community pharmacies is not accurate. Although, AMP has not yet been specifically defined; by definition, it will be substantially below our actual acquisition cost of generics that we purchase from wholesalers. Most retail pharmacies do not buy directly from manufacturers. We, like any other retail business, cannot sell a product below cost. Please issue a clear definition of AMP prior to instituting this regulation.

It may be that larger retail pharmacies (Walgreens, CVS, etc.) will be able to sustain this loss for a period of time. However, as they fill more Medicaid prescriptions, they to will have to turn away Medicaid patients. Obviously this will have a serious impact on supplying health care to Medicaid patients.

Respectfully,

Harry Taubman

Harry Taubman R.PH./owner

CMSO

27

610863

FEB 0 1 2007

Hans Vandergouw
3911 62nd Terrace East
Bradenton, FL 34203-7044
Ph (941) 866-8077 Fax (941) 866-8077 Cell (941) 730-0716

Ms. Leslie Norwalk
Centers for Medicare and Medicaid Services
Room 425H, Hubert Humphrey
200 Independence Ave., S.W.
Washington, DC 20201

Dear Ms. Norwalk, 11/22/06

As a pharmacist, I was recently informed about the drastic changes that are coming to pharmacy due to the enactment of the Medicaid reduction plan, which will be based on reimbursement formula thru the average manufacturer price (AMP).

If the present formula for reimbursement is allowed to take place, the potential death kneel for pharmacies across our nation may well take place "en mass" because of how the Center For Medicaid Services plans to define the reimbursement levels for generic drugs. The real danger is that the AMP formula calculation could drag reimbursement levels well below a pharmacy's cost to acquire the drugs. This will be absolutely disastrous for pharmacy. Not only that, but if precedent is set by your department for this to occur, the private sector will be inclined to follow suit, which will end retail pharmacy as we know it.

Already, pharmacy is being strained for "health care" dollars as never before. As an example, the current national average Medicaid dispensing fee is $4.15,yet according to a 2005 study by the University of Texas, the cost actual cost to dispense a prescription is $9.92, and does not even include a profit!

As a pharmacist who cares for the well being of not only my patients, but the health of my profession, I appeal to you to define AMP which will adequately cover the costs of pharmacy to do business in dispensing Medicaid prescriptions. As Stephen Schondelmeyer, PharmD, Ph.D. and professor at the Minnesota College of Pharmacy states so aptly, "*...pharmacies will face some tough choices. They can dispense more branded drugs (how can they do that under mandatory substitution laws), they can drop out of the Medicaid network altogether, although some pharmacies are dependant on Medicaid scripts. They can close up their business. Or they can try to hang on, while going broke one Medicaid script at a time.*"

I ask that you would do all you can to eliminate the calculation of the Medicaid reimbursement formula thru the average manufacturer price (AMP). There needs to be a more fair and equitable way. I look forward to your help.

Pharmaceutically yours,

Hans Vandergouw, R.Ph.

SHIRLEY B. GEIZE, R. PH.
ASSISTANT DIRECTOR
PURCHASING AND CONTRACTING

DEPARTMENT OF PHARMACY
600 North Wolfe Street / Carnegie 180
Baltimore, MD 21287-6180
410-955-0382 / FAX 410-955-0287
Email sgeize@jhmi.edu

THE JOHNS HOPKINS HOSPITAL

January 30, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

On behalf of Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center, we are responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Johns Hopkins Hospital (a 995 bed hospital) and Johns Hopkins Bayview Medical Center (a 345 bed hospital) are located in Baltimore, Maryland, and qualify as disproportionate share hospitals ("DSH") under the Medicare program. Each is enrolled as a covered entity under the federal 340B drug discount program.

Hospitals in the State of Maryland provide a unique circumstance to the proposed regulation to require reporting of NDC information on drugs administered in hospital outpatient settings. Regulated by the Maryland Health Services Cost Review Commission, we operate the 340B program under a Memorandum of Understanding with this independent commission of the Department of Health and Mental Hygiene. Savings from the 340B program (for all clinic administered drugs) are reported quarterly and this figure is used as a base to calculate the agreed upon rebate to the State of Maryland. This methodology allows a DSH hospital in Maryland to further its mission of serving the underserved while sharing the savings afforded by the 340B program with the citizens of Maryland through the rebate process.

Requiring NDC information would create enormous administrative and financial burdens for our hospitals. NDC numbers are not currently a data field element in the information passed from our pharmacy system to our billing system. Further, even though pharmacy systems are built to incorporate the NDC providing clinical checking that helps to safeguard patients from adverse events due to drug interactions, the numbers may only represent a generic equivalent. Maintenance of the NDC database, building a new infrastructure and/or creating new interfaces between current information systems would require significant resource and time, substantially reducing the program benefit. Enactment of this regulation would result in no gain for the State of Maryland, since we currently share our benefit. If federal regulation compels NDC reporting despite existing arrangements with state governments, everyone will lose.

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result. We would be happy to speak with you directly if you require clarification of any information contained herein.

Sincerely, Shirley B. Geize

Shirley B. Geize, R.Ph.
Purchasing and Contracting for Pharmacy
Johns Hopkins Hospital
410-955-0382
sgeize@jhmi.edu

Nancy Tzeng, Pharm D.
Director of Pharmacy
Johns Hopkins Bayview Medical Center
410-550-0962
ntzeng@jhmi.edu

>statute, rule, regulation or other directive that may be applicable to
>the requestor.
>
>>-----Original Message-----
>>From: Shukla, Tejas H. (CMS/CMSO)
>>Sent: Monday, February 12, 2007 2:41 PM
>>To: SEXTON, GAIL (CMS/CMSO)
>>Cc: Khau, Meagan T. (CMS/CMSO); Freeze, Janet G. (CMS/CMSO)
>>Subject: FW: RightNow Service Notification
>>
>>Gail,
>>  I am sending this for you review.  Please forward as
>necessary.  Thank
>>you.
>>
>>Tejas Shukla
>>>----------
>>>  Summary: As a manager to an independent pharmacy
>for over 12
>>>  years I have seen the the...
>>>  Product Level 1: Medicaid
>>>  Product Level 2: Medicaid Prescription Drugs  Product Level 3:
>>> Medicaid Drug Rebate Program
>>>  Date Created: 02/12/2007 11:26 AM
>>>  Last Updated: 02/12/2007 11:26 AM
>>>  Status: Unresolved
>>>  Assigned: Tejas Shukla
>>>  State:
>>>
>>>
>>>Discussion Thread
>>>----------
>>>Customer - 02/12/2007 11:26 AM
>>
>>>As a manager to an independent pharmacy for over 12 years I
>have seen the
>>>the income levels regarding the reimbursement for prescriptions drop
>>>considerably. However, none have been as dramatic as the
>implementations
>>of
>>>the Medicaid Drug Rebate Program provisions of the Deficit
>Reduction Act
>>>suggest. By instituting the AMP-based FULs it has been estimated that
>>>reimbursement levels will fall 65 percent lower than the
>acquisition costs
>>>we pay for generic medications. (GAO-07-239R, p.3) Even
>worse, the cost of
>>>filling prescriptions, estimated at $10.79 per prescription at our
>>pharmacy
>>>will be another risk to potential loss with the enactment of
>the Medicaid
>>>Drug Rebate Plan.
>>>
>>>If this is implemented, our only options may become to
>either work with
>>>doctor's offices in switching patients to name brand
>medications in which
>>>we will at least cover cost or simply discontinue our
>Medicaid services in
>>>an area where it is much needed. Being located across the
>street from a
>>>shelter and working with a local clinic in assisting patient
>care, our
>>cost
>>>to survive is riding on the contention that AMP is not
>appropiate as a
>>>baseline for reimbursement unless it includes pharmacies

>acquistion costs.
>>>
>>>If AMP is applied as the baseline for reimbursement and an index for
>>>rebates it will serve two distinct and contrary purposes: 1)
>as a baseline
>>>for pharmacy reimbursement, and 2) as an index for
>manufacturer rebates
>>>paid to states. AMP was never intended to serve as a baseline for
>>>reimbursement and may not have been an effective measure as
>outlined in
>>the
>>>report "Medicaid Drug Rebate Program--Inadequate Oversight
>Raises Concerns
>>>about Rebate Paid to States" (GAO-05-102).
>>>
>>>I ask that you please take into consideration our level of
>the health care
>>>industry when making this final decision. An accurate
>definition of AMP
>>and
>>>Best Price will not only lead to greater rebates to state Medicaid
>>>agencies, but also an accurate baseline for adequate reimbursement
>>>necessary for our store's survival and that of thousands of other
>>>pharmacies.
>>>
>>>Thank you for consideration.
>>>Sincerely,
>>>Cherie Poirier
>>>Daniel's Pharmacy
>>>860-779-1136
>
>

## Hayes, Yolanda K. (CMS/OSORA)

**From:** Watchorn, Marge L. (CMS/CMSO)
**Sent:** Tuesday, February 13, 2007 9:02 AM
**To:** Johnson, Sharon B. (CMS/OSORA); Hayes, Yolanda K. (CMS/OSORA); Bryson, Stacey L. (CMS/OSORA)
**Cc:** Reed, Larry L. (CMS/CMSO); Duzor, Deirdre D. (CMS/CMSO)
**Subject:** FW: RightNow Service Notification

Good morning,

We received a public comment via the RightNow Q&A service on the CMS website. Please enter this into the public comment log for CMS-2238-P.

Also, do we have an update on the number of public comments received to date?

Thanks,
Marge

>-----Original Message-----
>From: SEXTON, GAIL (CMS/CMSO)
>Sent: Tuesday, February 13, 2007 8:11 AM
>To: Cooper, Cheryl C. (CMS/CMSO); Duzor, Deirdre D.
>(CMS/CMSO); Fine, Joseph L. (CMS/CMSO); Howell, Kimberly M.
>(CMS/CMSO); Khau, Meagan T. (CMS/CMSO); Kruh, Madlyn F.
>(CMS/CMSO); Leeds, Bernadette W. (CMS/CMSO); Lyon, Christina M.
>(CMS/CMSO); Reed, Larry L. (CMS/CMSO); Reese, Yolanda (CMS/CMSO);
>SEXTON, GAIL (CMS/CMSO); Watchorn, Marge L. (CMS/CMSO)
>Subject: FW: RightNow Service Notification
>
>
>I received this e-mail comment on the reg via the "Right Now"
>web Q/A system - how should we handle written comments that come in via
>this system, (or via direct e-mail) which are outside of the submission
>requirements stated in the reg?
>
>I am cc: everyone on this inquiry, so if any of us receives similar
>comments outside of the normal submission guidelines, we will know how
>to proceed.
>
>Thanks,
>Gail
>
>Gail Sexton
>Health Insurance Specialist
>Centers for Medicare and Medicaid Services Division of Pharmacy 7500
>Security Blvd. M/S S2-14-26 Baltimore, MD 21244-1850
>(410)-786-4583
>FAX (410)-786-5882
>gail.sexton@cms.hhs.gov
>
>
>
>Any opinion [or response] expressed in this e-mail is informal and will
>not bind or obligate CMS. In responding to this question [or, in
>issuing this response], we have relied solely on the facts and
>information presented to us. We have not undertaken an independent
>investigation of the materials presented. This response [or "opinion"]
>is limited to the facts and information presented. We expect that all
>material facts have been fully, completely, and accurately presented.
>The failure to disclose, or the misrepresentation of, any material
>facts or information may alter the [opinion or response]. This e-mail
>is applicable only to the Medicaid rebate statute, 42 U.S.C. Section
>1396r-8, and it does not address any other federal, state, or local

# Congress of the United States

## U.S. House of Representatives

### Committee on Small Business

2361 Rayburn House Office Building

Washington, DC 20515-0515

February 23, 2007

Acting Administrator Leslie Norwalk
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Hubert M. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Comments on Proposed Rule Implementing the Provisions of the Deficit Reduction Act of 2005 Pertaining to Prescription Drugs Under the Medicaid Program. 71 Fed. Reg. 77174, December 22, 2006.

File Code: CMS-2238-P

Dear Acting Administrator Norwalk:

I am writing to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule implementing the provisions of the Deficit Reduction Act of 2005[1] (DRA) pertaining to prescription drugs under the Medicaid program (the "Proposed Rule").[2]

The Proposed Rule implements the average manufacturer price (AMP) as the new basis for the Federal upper limit (FUL) for multiple source prescription drugs.

These comments focus on the impact of the Proposed Rule on small retail pharmacies (the "Impact Analysis" section). The Proposed Rule will impact small retail pharmacies in a disparate manner. Unfortunately, CMS has not contemplated the impact of this regulation on small businesses to the extent it is obligated to do so pursuant to the Regulatory Flexibility Act (RFA).[3]

---

[1] Pub. L. No. 109-171
[2] 71 Fed. Reg. 77174, December 22, 2006
[3] 5 U.S.C. § 601 et. seq.

The RFA requires regulatory agencies to estimate the impacts of proposed rules on small entities such as small businesses. The RFA mandates that agencies conduct an initial regulatory flexibility analysis on all rules having a significant economic impact on a substantial number of small entities. CMS has stated that the Proposed Rule will have such an impact.[4]

The initial regulatory flexibility analysis in the Proposed Rule is insufficient for the following reasons including, but not limited to:

**1. CMS Did Not Adequately Contemplate the Impact of the Proposed Rule on Small Retail Pharmacies**

The initial regulatory flexibility analysis on the impact of the Proposed Rule on small retail pharmacies is inadequate because CMS is analyzing the retail pharmacy industry as a whole and not examining the small business sector of the industry independently.

In a report dated December 22, 2006, the GAO found that an AMP-based FUL will fall an average of 36% below pharmacy acquisition costs for multiple-source outpatient prescription drugs.[5] This model will shift a significant cost burden onto the states, who will likely in turn set reimbursement below pharmacy cost. Independent pharmacists and pharmacies dispense approximately 42% of the nation's retail prescription drugs.[6] According to the National Community Pharmacists Association, nearly 80% of independent pharmacies have revenues of less than $6 million.[7] This classifies the majority of independent pharmacies well within the Small Business Administration's size standards of small business. If pharmacies are forced to close as a result of inadequate reimbursements, all patients – not just Medicaid patients – will suffer.

These studies are in sharp contrast to the findings in the Proposed Rule in which CMS estimates that:

> [T]he effect of the proposed rule would be to reduce retail prescription drug revenues by less than one percent, on average. Actual revenue losses would be even smaller for two reasons. First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as prescription drug sales.[8]

---

[4] 71 Fed. Reg. at 77191

[5] U.S. Gen. Accounting Office, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, GAO-07-239R (December 22, 2006).

[6] http://www.ncpanet.org/aboutncpa/ipt.php

[7] 2006 NCPA-Pfizer Digest

[8] 71 Fed. Reg. at 77192-93

This conclusion does not adequately consider the sales statistics of small retail pharmacies because CMS is analyzing the retail pharmacy industry as a whole. CMS is not quantifying the impact upon small, independent retail pharmacies. Independents serve a disproportionate percentage of Medicaid beneficiaries. In fact, over 20% of the average independent retail community pharmacy's business is devoted to serving their Medicaid patients and 92% of their entire business consists of prescription drug sales.[9] Independent pharmacies have significantly less prescription and non-prescription revenues than traditional chain, grocery store and mass merchant pharmacies.

According to the National Community Pharmacists Association, 86% of pharmacies are seriously considering dropping out of the Medicaid program if the CMS-proposed formula goes into effect.

The initial regulatory flexibility analysis does not consider that independent pharmacies service a disproportionate amount of Medicaid patients and have significantly less prescription and non-prescription revenues than traditional chain, grocery store and mass merchant pharmacies. The RFA requires that CMS contemplate these factors.[10]

**2. CMS Did Not Adequately Evaluate Alternatives to the Proposed Rule to Minimize the Economic Impact on Small Entities**

The RFA requires that each initial regulatory flexibility analysis contain a description of "any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities."[11]

The initial regulatory flexibility analysis makes no effort to describe significant alternatives to the Proposed Rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the Proposed Rule on small entities as required by the RFA.

Options for reducing this impact include exempting small retail pharmacies from the new reimbursement formula, creating a separate reimbursement formula for small retail pharmacies, or exempting pharmacies if their percentage of Medicaid business exceeds 10%.

Small retail pharmacies play a critical role in serving rural and inner-city communities—many of which are home to significant numbers of Medicaid recipients. CMS should use the discretion granted the Secretary in the DRA to publish a final rule that does not harm small retail pharmacies and the communities they serve.

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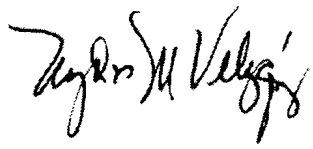
[9] 2006 NCPA-Pfizer Digest

[10] "The [initial regulatory flexibility analysis] shall describe the impact of the proposed rule on small entities." 5 U.S.C. § 603

[11] 5 U.S.C. § 603

In conclusion, as the chairwoman of the committee which oversees the RFA, I believe CMS must revise its initial regulatory flexibility analysis to take into account the issues impacting small retail pharmacies discussed in these comments. The public should then be given an opportunity to comment on the revised initial regulatory flexibility analysis. Small businesses are entitled to be fully aware of the impact that regulations will have on them and your regulatory promulgation process will be stronger and better informed by the effort. Should your staff have any questions concerning these comments, please do not hesitate to contact the Committee's regulatory counsel, Erik Lieberman, at 202-225-4038. Thank you for your consideration in this matter.

Sincerely,



Nydia Velázquez
Chairwoman
House Small Business Committee

Cc: Acting Administrator Steven D. Aitken, Office of Information and Regulatory Affairs, Office of Management and Budget

# *Bremo LTC Pharmacy*

*Specializing in Pharmacy Care*

*Richmond Apothecaries Inc.*

R. Keith Kittinger, F.A.C.A. Pharmacist | Catherine Cary, PharmD Pharmacist | Teena Hucul, Pharmacist | Michelle Shibley, PharmD Pharmacist


February 7, 2007

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

Gentlemen:

As a pharmacist serving the most needy, the frail elderly and mental health populations, under Medicaid in Virginia for 35 years, I share your concern about the rising costs and utilization of pharmaceuticals. When I first began in pharmacy, an expensive prescription was $ 10. Now we have prescriptions that are $ 1,800 per month.

Several things strike me about the proposed change in reimbursement for generic drugs. First, we, the pharmacists of this country, are just as concerned about costs and yet we have not really been called upon to give ideas or use our knowledge to help with cost containment. We have done a very good job of maximizing the use of less expensive generic drugs. However, there are so many other ways that we could contribute if allowed and if given the incentive to do so.

My pharmacy is a small, family operated independent operation. We provide long term care services to the frail elderly and mental health patients who reside in group homes and assisted living facilities. We provide special compliance packaging to insure that the correct medication is given at the correct time. We provide oversight both at the pharmacy before medications are filled and in the facility to make sure that the medications are being used correctly in the home. We also provide delivery of these medications without charge. This has become quite a burden with the increasing cost of fuel since we have no way to recoup these costs. Unfortunately, many 3rd parties including Medicaid do not recognize the value of our services. Therefore, we have to survive within the reimbursement that is available to us. Any reduction in reimbursement will threaten our ability to survive and continue to serve this needy population.

Let me give you one typical example of a patient who I serve. LR is a 48-year-old female with schizophrenia and severe diabetes. I have actually been to her home to help her learn to test her blood sugars and have worked closely with her doctor to develop a plan to keep her diabetes under control. So far, LR has not developed any end stage organ problems despite the fact that she is mentally ill and has severe diabetes. We have aggressively worked with her and her outcomes have been good to date.

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My second concern involves the redefinition of the cost basis for generic drugs. Since generic drugs constitute a small percentage of the Medicaid expense, it seems that you are attacking the wrong sector. The branded pharmaceuticals are where the costs really are. An extra rebate, even a small rebate, from the branded drugs will have a far greater saving for the Medicaid/Medicare programs that the proposed AMP for generics. Simple economics tells us that.

Let's look at the branded pharmaceutical market. The branded companies always fight any kind of cost containment under the umbrella of "research and development". While it is true that it is expensive to develop new drugs, what they don't like to talk about is the fact that the branded companies spend as much money on "marketing" these drugs as they do on research and development. Watch any 30-minute news and see how many prescription drugs are advertised. Who do you think is paying for all this advertising? The branded companies also provide lavish dinners for doctors and pharmacists in the name of "education". I am sometimes embarrassed to see how much money they spend on this when I think of the people who are struggling to afford their medications and the Medicaid programs, which are imploding on pharmaceutical costs. Be assured that the pharmaceutical industry is big and powerful and will fight any attempt to block their free right to charge what they want and market and create demand for their products in the name of "education". Health care is beginning to move away from a free market commodity and into the public welfare sector like education and fire and police protection.

Regarding the definition of AMP, I see a number of problems. The formula will include mail order and hospital pharmacies which have historically been able to get better prices that the rest of us. That is inherently unfair. The dispensing fee issue is not addressed. We estimated it costs between $ 10 and 11 per prescription for us to provide the services that we feel are absolutely essential for the best outcome of the patient. Please notice that I did not say for providing the drug. Providing the best outcome is the goal. Sometimes, <u>not</u> giving the patient a particular medication would provide a better outcome. Imagine paying pharmacists for stopping unnecessary medications! The GAO report estimates that the average reimbursement for generic prescriptions will decrease 36%. CMS counters that most pharmacies have "other sales" that they can count on and increased volume to make up the lost. First, my pharmacy dispenses only two things: medications and information. We have no "other sales". Secondly, any system that becomes volume driven is not quality driven. We want to provide the best outcomes possible, not the most prescriptions per day.


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# *Bremo LTC Pharmacy*

*Specializing in Pharmacy Care*

*Richmond Apothecaries Inc.*

R. Keith Kittinger, F.A.C.A. Pharmacist | Catherine Cary, PharmD Pharmacist | Teena Hucul, Pharmacist | Michelle Shibley, PharmD Pharmacist


Again, my concern is with any scenario that reduces my limited reimbursement for providing high quality pharmacy services to the most sick, the medically needy in the Medicaid population. We are struggling to survive in today's low margin environment. Any further erosion of our margins will likely cause many pharmacies to go out of business and the services that they provide for the Medicaid patients will go away. These needy patients cannot be served by mail order pharmacy or chain pharmacies. They people like us who are dedicated to the well-being.

I know that the branded pharmaceutical companies will block any attempts to get cost savings from them. We are a small group as independent pharmacies and therefore a much easier target. The people we serve also do not have political clout. I really think that working with pharmacists, CMS could come up with better ways to save costs and improve outcomes. Medication therapy management (MTM) is certainly one way but it is very limited in the Medicare program and the private, for profit plans have complete control over this process. I hope that you will delay this plan and give the "little people" a chance to contribute to a better, most cost efficient system.

Sincerely,

R. Keith Kittinger, F.A.C.A
Pharmacist


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**Anthony J. Principi**
Senior Vice President
Government Relations

February 15, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: **Proposed Rule – 42 CFR Part 447**
**File Code: CMS-2238-P**

Dear Ms. Norwalk:

I am pleased to share with you input to the proposed rule (CMS-2238-P) that was published in the December 22, 2006 *Federal Register*, that would implement provisions of the Deficit Reduction Act (DRA) related to prescription medication coverage under Medicaid. In summary, there are three DRA issues that Pfizer addresses in these comments – the base average manufacturers price (AMP) used for calculating the CPI rebate; the method for including authorized generic prices in the calculation of Medicaid rebates; and the definition of the AMP.

Our specific comments are attached. We would be pleased to have the opportunity to speak further with you and your staff about these recommendations.

Sincerely,

Anthony J. Principi
Senior Vice President, Government Relations

**Deficit Reduction Act Proposed Rule – CMS-2238-P**
***Recommendations from Pfizer Inc.***
**February 15, 2007**

Pfizer submits the following comments on the proposed rule (File Code: CMS-2238-P, 74 Fed. Reg. 77174 (December 22, 2006)) that will implement Medicaid provisions of the Deficit Reduction Act (DRA) as they pertain to prescription medications.

- **Base Date AMP and the CPI Rebate** – As part of the DRA, Congress called for the exclusion of prompt pay discounts when calculating the AMP. The statute does not clarify whether a corresponding adjustment should be made to the base date AMP from which the CPI rebate is calculated. In addition, CMS recommends that manufacturers be allowed to revise their base date AMP for other measures to be used in the new calculation of the base date AMP. In either situation, Pfizer has found some of the historical information related to the base date AMP to be unreliable or unavailable. This is compounded by the fact that Pfizer has acquired several pharmaceutical manufacturers since the introduction of the Medicaid rebate program.

  Therefore, we recommend that, in the absence of complete historical data that would allow a manufacturer to precisely recalculate the base date AMP, a manufacturer should be minimally allowed to adjust the base date AMP based on current prompt pay business practices. This may be achieved by:

  1. Adjusting the base date rebate AMP by an amount comparable to the prompt pay discount currently offered in the marketplace by the manufacturer; or

  2. Applying a flat 2 percent upward adjustment to the base date AMP, reflecting the industry's typical historical prompt pay discount.

  This new baseline would then be utilized in calculating the CPI rebate beginning with the first quarter of 2007 when the new AMP calculations will be required.

  Our recommendation is based on Pfizer's belief that Congress intended to ensure consistency among all manufacturers in the calculation of the AMP by eliminating the prompt pay discount from the AMP calculation, not to penalize brand manufacturers for historic prompt pay discounts. Accordingly, we recommend that an appropriate adjustment be applied to the baseline AMPs to provide comparability and symmetry between the pre-DRA and post-DRA AMP calculations.

  In addition, we wish to address the CMS commentary raised in the preamble of the proposed rule (page 77191). Specifically, CMS commented that it has no information as to the percent of sales that qualify for prompt pay discounts. At Pfizer, we have historically offered a 2 percent prompt-pay discount as part of our business practice. Based on a review of our internal records, we find that over 95 percent of our customers qualify for our prompt pay discount and approximately 98 to 99 percent of those customers receive the discount. An assessment of the potential impact on the

market may be inferred from 2005 Pfizer prescription sales based on dollar volume, which accounted for 16.5 percent of the overall U.S. prescription drug market.

***Recommendation Summary:*** 1) Adjust the baseline AMP by an amount equal to the prompt pay discount currently offered in the marketplace by the manufacturer; or 2) implement a flat 2 percent adjustment to the base date AMP. Such an approach should be allowed even in the absence of complete historical data on the other components of the AMP, without the need for a complete recalculation.

- **Rebate Implementation Issues and Authorized Generics** – The DRA provides that the prices of so-called "authorized generic" drug products ("AGs") should be included in calculations of the branded manufacturer's "best price." The DRA does not direct how AG prices should be incorporated into best price calculations, and thus the question was left to CMS to resolve by rulemaking. CMS now proposes a quarterly calculation that would operate, in many cases, as a severe and potentially disabling penalty against AG sales. As discussed more fully below, this approach is inconsistent with the congressional purpose underlying the DRA and contrary to the public interest in the administration of best price rebates.

  Best price rebates allow government programs to share in the price benefits that drug manufacturers make available to private purchasers of branded products. Before the DRA, AGs were not included in best price calculations for branded products because—as CMS recognized—AGs are not branded products, but are generic products that are sold into a distinct generic drug market at significantly lower prices than the branded drug, in competition with other generic products. Thus, AGs carried their own best price, with rebates set accordingly.[1]

  Although the DRA directs CMS to include AG prices in best price calculations for branded drugs, nothing in the DRA suggests that Congress intended to penalize – much less paralyze – the authorized generic industry. To the contrary, circumstances surrounding Congress' passage of the DRA, the DRA itself, and continuing legislative developments make clear that Congress' intent—and the best public policy—at this juncture is to take care to preserve AGs and incorporate them positively into the best price program pending further legislative direction. Moreover, at Congress' request, FTC is currently conducting an expansive study of AGs.[2] It would be premature and unwise of CMS to adopt any policy that would impose a penalty on the AG industry before the conclusions of that study are in hand.

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[1] Because CMS has classified AGs as "innovator multisource drugs," rebates for AGs are higher than the rebates paid for non-AG generic products. *See* 42 U.S.C. § 1396r-8(c)(1)(B)(1)(V), (c)(3)(B)(ii)

[2] In May 2005, Senators Grassley, Leahy, and Rockefeller have requested that FTC conduct a study of "the short term and long term effects on competition of the practice of 'authorized' generics." *See* FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, Mar. 29, 2006, www.ftc.gov. Subsequently, Representative Waxman requested the Commission study 'the impact of so-called 'authorized generics' on competition in the prescription drug marketplace." *Id.*

The DRA itself should be read as an endorsement of, rather than an attack against AGs. As noted, the DRA embraced AGs as a means for enhancing best price policies. CMS should ensure that its implementation of the DRA's provisions do not have the effect of destroying the AG industry.

Circumstances both leading up to and following enactment of the DRA also should guide CMS' approach. Prior to enacting the DRA's provision on AGs, Congress held no hearings and referenced no reports assessing the broader benefits and costs of AGs. Indeed, recognizing that significant questions about AGs needed to be addressed, several legislators expressed the need for congressional hearings and requested an FTC study of AGs.[3] Moreover, the congressional conference committee for the DRA delayed the DRA's effective date to allow more time for Congress and affected regulatory agencies to undertake a thorough policy evaluation of the impact of AGs.[4] Still today, however, the necessary assessments have not been completed: the FTC is study is still ongoing, and Congress has still not held legislative hearings.

Because the DRA itself embraces AGs, and because no evidence has been produced demonstrating that AGs require regulation and restriction, CMS would be remiss to adopt any approach that would restrict or eliminate AGs.[5] Rather, in determining the appropriate approach for integrating AGs into best price calculations, CMS must ensure that it does not limit or injure the availability of AGs. Pfizer respectfully submits that the approach CMS has proposed would in fact severely penalize, and thus deter, sales by AGs. Thus, Pfizer recommends that CMS alter this approach, as explained below.

The DRA defines "best price" as the "lowest price available from the manufacturer during the rebate period" for "any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act" Under its proposed rule, CMS would define the rebate period as the calendar quarter, 71 Fed. Reg. at 77177, and would apply the AG price for the full quarter no matter when in the quarter the AG launched. *Id.* at 77185. CMS bases this proposal on its previous practice and on a statutory definition of "rebate period" predating the DRA. *Id.* at 77177. The best price statute, however, does not require that the rebate period be a calendar quarter. Rather, it explicitly provides CMS with authority to designate another period. 42 USC § 1396r-8(k)(8) (defining rebate period as "a calendar quarter or other period specified by the Secretary"). In order to avoid an undue penalty against sales of AGs, Pfizer submits that CMS divide the first

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[3] In May 2005, Senators Grassley, Leahy, and Rockefeller have requested that FTC conduct a study of "the short term and long term effects on competition of the practice of 'authorized' generics." *See* FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, Mar. 29, 2006, www.ftc.gov. Subsequently, Representative Waxman requested the Commission study 'the impact of so-called 'authorized generics' on competition in the prescription drug marketplace." *Id.*

[4] *See* H. Rep. 109-362 at 264-65 (explaining that as per conference agreement, effective date of legislation would be January 1, 2007 rather than January 1, 2006 as proposed in the House and Senate bills).

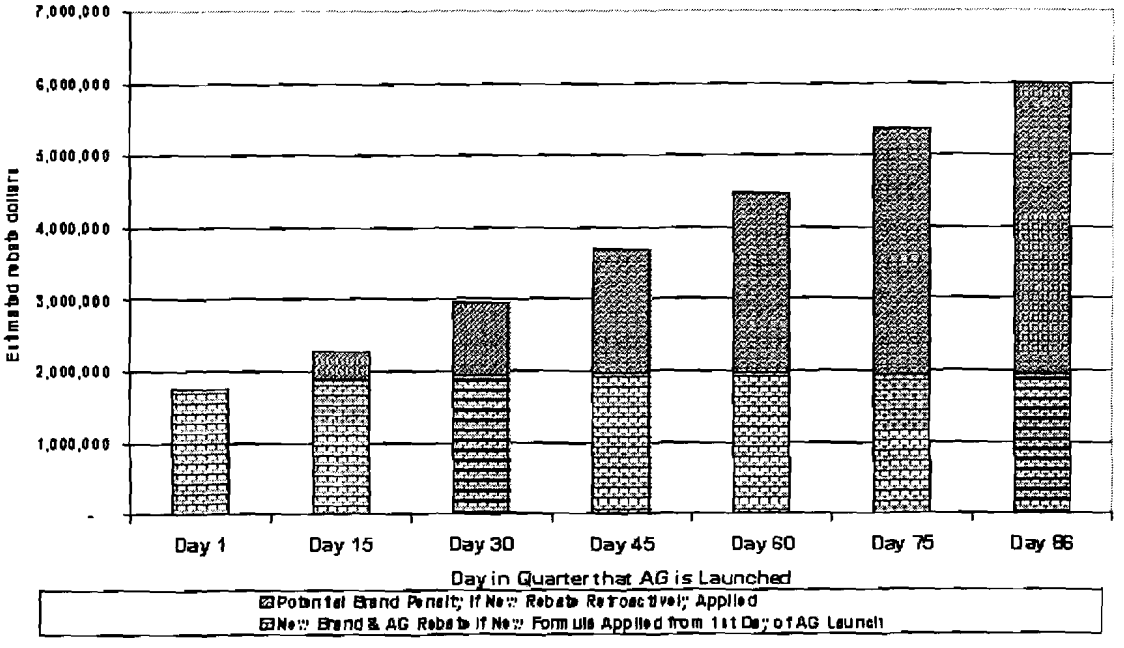
[5] The recent introduction of legislation that would ban AGs, *see e.g.*, S. 438 (110 Cong. 2006), further confirms that the DRA itself was not intended to restrict or eliminate sales of AGs.

quarter in which an AG launches into two separate rebate periods: 1) one period prior to the launch of the authorized generic; and 2) one starting at the date of the launch. Alternatively, for the first quarter of the authorized generic entry, manufacturers could be permitted to report an AMP and weighted best price based on the number of days the AG is available in the quarter. As a third option, the calculation of the best price incorporating the authorized generic could begin with the first full quarter during which the authorized generic is available.

Under CMS' proposal, there would be a huge disincentive to launching an authorized generic during the quarter in which brand exclusivity is lost. Irrespective of when in a calendar quarter an AG launches, the proposed rule would establish the AG price as the best price for the brand for the entirety of that quarter. As the following graphic shows, the later in the quarter such a launch took place, the greater the potential for a more significant penalty this approach would impose on the brand manufacturer. This is because the brand would retain a larger share of sales during the quarter given the timing of the generic entry. At the same time the change in the best price would be in place for a shorter period of time although it would be applied to the full first quarter.

**Retroactive Application of Rebate During the First Quarter Results in a Penalty Based on the Timing of an AG Launch in the Quarter.**

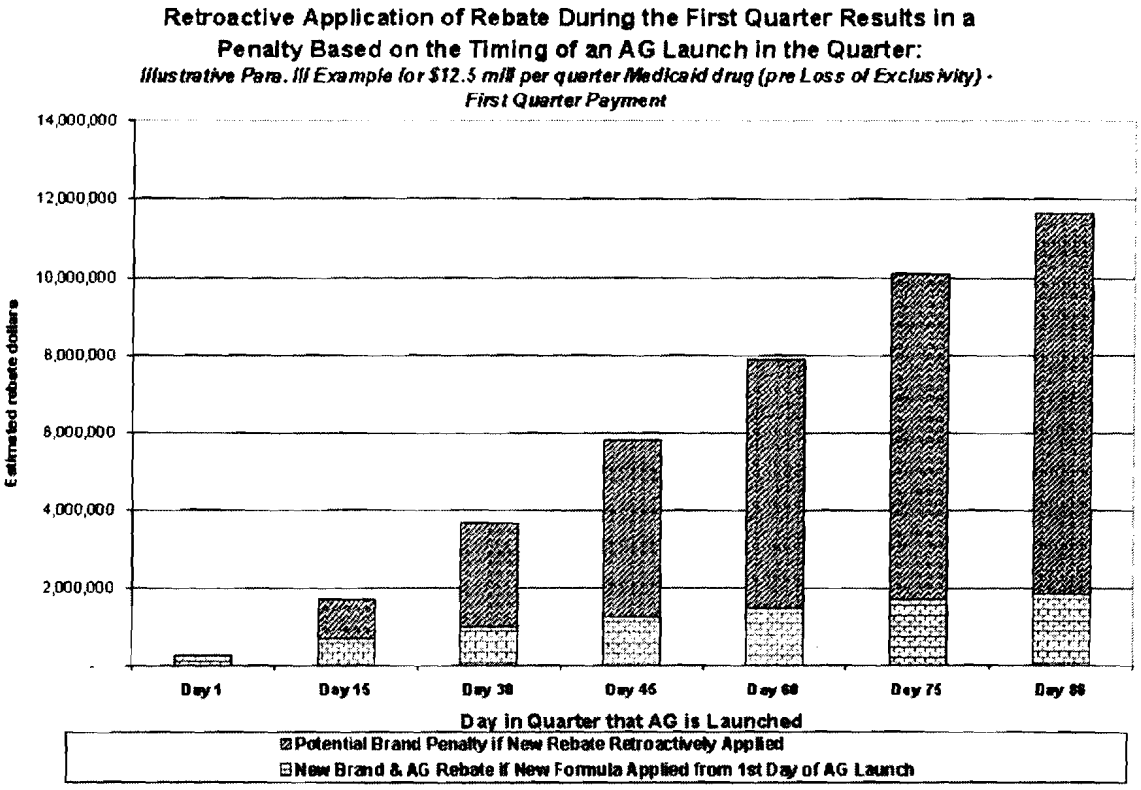
*Illustrative Para. IV Example for $125 mill per quarter Medicaid drug (pre Loss of Exclusivity) - First Quarter Payment*




Source: Internal Pfizer Analysis, 2006. *Illustrative example.*

Using the same base model for a Paragraph III launch, as shown in the following graph, the disincentive for an AG to enter the market is even more pronounced given the rush of other generics onto the market. This model uses the same product with adjustments made for changes that would be expected in the market during this type

of product launch. For purposes of the illustration, it was assumed that six generic drugs entered the market at the same time as the AG.




Source: Internal Pfizer Analysis, 2006. *Illustrative example.*

To illustrate with a real life example, Pfizer has a product where exclusivity is expected to be lost late in the calendar quarter. There is expected to be no 180-day exclusivity for this product. Thus, upon the loss of exclusivity, we expect to launch an authorized generic at the same time that multiple ANDA generics would enter the market. Based on current generic market pricing trends when there are multiple competitors, the rebate penalty to the brand is expected to be three times the forecasted year-end revenue. It is not clear to what degree a business model can sustain a revenue stream that pays out more than it brings in. For now, Pfizer is committed to launching NDA products as generics through its Greenstone division in response to single or multiple competitor entrants. However, to make sure that authorized generics remain an important part of the marketplace for patients, brand manufacturers should not be unfairly penalized.

Furthermore, based on recent research by IMS[6], a delay in the launch of an authorized generic has the potential to raise generic prices for Medicaid. This is based on two factors. First, IMS showed that generics that launched in the presence of an AG saw an extra 15 points in savings over the brand when compared to a generic launch without an AG in the market. Thus, without an AG entry, the net price of future

[6] IMS Consulting. *Assessment of Authorized Generics in the U.S.* Spring 2006. ©2006, IMS Health.

generics entering the market during a Paragraph IV filing would be higher, resulting in higher costs for Medicaid and the public at large.

Second, AGs must already pay a minimum 15.1 percent or best price rebate to Medicaid while ANDA generics are only subjected to a flat 11 percent rebate. As a result, equivalently priced generics (AG v. ANDA generics) would be cheaper to Medicaid as a result of required higher rebate payments on the part of the AG. In the absence of AGs, that additional savings would not be realized adding costs back into the Medicaid program. The following table summarized the relative rebates that are required by Medicaid.

**Comparison of Medicaid Rebate Requirements**

| | Brands | Authorized Generics | Generics |
|---|---|---|---|
| Base / Minimum Rebate | 15.1% | 15.1% | 11.0% |
| Best Price Rebate | Yes | Yes | No |

We believe an approach must be considered that brings fairness to this program. As noted in the definitions section, the "*Rebate Period* is defined in section 1927(k)(8) of the Act as a calendar quarter or other period specified by the Secretary..." Since the rebate period definition allows flexibility on the rebate period definition, it is our interpretation that the Secretary can and should redefine the rebate period for this new situation not contemplated when the original rebate law was established.

We further believe that failure to allow for this revision during the initial launch of an authorized generic will result in an unintended penalty on the brand medication, is unreasonable and an unacceptable approach for reasons stated.

***Recommendation Summary:*** Three options should be considered to address the brand authorized generic rebate penalty:

1) During the first quarter in which an authorized generic is launched, a new rebate period could be defined, such that there are two distinct time periods: a) one period prior to the launch of the authorized generic; and b) one starting at the date of the launch. A commensurate change in the new DDR system will be needed to allow for appropriate reporting to CMS. By allowing this definition, a manufacturer would be able to apply an AMP and weighted best price for the first quarter of the AG entry;
2) For the first quarter of the authorized generic entry, manufacturers could be permitted to report an AMP and weighted best price based on the number of days the AG is available in the quarter; or
3) Calculation of the best price incorporating the authorized generic could begin the first full quarter during which the authorized generic is available.

Any of these options would eliminate the unintended rebate penalty, while ensuring that the Medicaid program benefits from the lower prices and higher rebates that flow from the prompt entry of authorized generics into the marketplace. Pfizer submits that CMS should redefine the rebate period following the initial launch of an authorized generic in a manner which is consistent with the congressional intent of incorporating the AG best price in the brand calculation and which also recognizes, but does not prejudge the outcomes of the existing and continuing FTC and Congressional assessments of AGs.

- **Definition of the Average Manufacturers Price** – Pfizer has been an industry leader in carefully applying the provisions of OBRA-90 and OBRA-93 with regard to the calculation of the average manufacturers price (AMP). We appreciate the new guidance included in the proposed rule. However, there are a number of issues that we believe need further clarification. In addition, there are other issues related to the AMP calculation that should be reconsidered based on technical aspects and marketplace implications of the proposed rule. The following issues represent our primary recommendations on this issue:

    - *Authorized Generic/Brand Price Blending* – Further clarification is needed regarding methods for combining authorized generic and brand AMPs for both monthly and quarterly calculations, notwithstanding our previous comments on this issue. We recommend that the manufacturer of the authorized generic separately calculates AMP and AMP-eligible units, which are used to derive the blended AMP using a weighted average of that data and the branded product's AMP and AMP-eligible units. Wholesale incorporation of the authorized generic's raw sales data would not be required. Additionally, we request clarification on the steps a brand manufacturer should take if the required data is not received in time from the authorized generic company, in order to calculate and submit the blended data. We recommend allowing use of the prior month's data to calculate the blended AMP to ensure compliance with reporting deadlines.

    - *AMP and Pharmacy Payments* – Given the recent guidance sent to the states (Release No. 144) for the purposes of reevaluating dispensing fees for pharmacists, we believe it is important that the ingredient payment for which there is only a single manufacturer be sufficient to cover the full cost of the medication and related expenses to the pharmacy. Reports such as the CBO paper "Prescription Drug Pricing in the Private Sector" (January 2007), clearly point to the different market dynamics between the brand and generic industries with regard to pricing, and also to the pricing variability within the multiple source market. These dynamics and their impact should be carefully considered and accounted for in the final regulations.

      Furthermore, we find that other government programs, such as the State Children's Health Insurance Program (SCHIP) and the State Pharmaceutical Assistance Programs (SPAP), pay pharmacies based on the AMP calculation.

At the same time, the prices to these programs are included in the calculation, thereby iteratively lowering the AMPs. Based on our experience, we also find that discounts to PBMs, SCHIP and SPAP programs are not readily available to pharmacies, thus, predicating reimbursement on an AMP which incorporates these discounts, presumptively understates the 'acquisition' cost to the pharmacy.

Therefore, we recommend that CMS: 1) reconsider the inclusion criteria for sales and discounts in the calculation of branded AMPs; and 2) consider the financial ramifications to pharmacies in the event branded AMPs become the basis for pharmacy reimbursement.

- *Estimating Rebates for Monthly AMPs* – We believe that further clarification and guidance is needed regarding appropriate methods of estimating rebates for the monthly AMP calculations, including whether estimations are required or not. We have found that rebate data is often delayed, sometimes by many months. If accurate rebate data is to be included in the calculation on a monthly basis, an estimation method must be used. We propose looking at the actual rebates as a percent of total AMP sales during the four quarters, beginning with the quarter two before the quarter the current month falls into, and the previous three quarters (i.e. monthly calculations for April would use prior year January-December discount rates). This percent can then be applied to the sales used in the current month's calculation to accurately estimate a rebate total for that time period.

- *Rebate and Discount Aggregation for Best Price* – We would like to request further clarification regarding the practice of aggregating or disaggregating various rebates and discounts for a particular product, when multiple customers are present in the product sales chain. We feel that it would not only be inappropriate, but also technically unfeasible to aggregate discounts to various unrelated customers. This would produce a "best price" clearly well below the price truly offered to any specific customer. It would be virtually impossible to ensure rebates and discounts between different customers were accurately mapped back to the correct units. Therefore, we believe the disaggregate reporting of best price represents the *true* best price of the product given technical capability, business policy decisions, and business disclosure limitations and controls (i.e., customer discounting policies which are unknown to the manufacturer).

- *Rebate Bundling* – Further clarification is needed regarding how to treat rebates given to multiple products that are technically bundled together. The proposed regulation suggests that the discounts are to be "allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement." Attempting to allocate rebate dollars between such products would be a tremendous administrative and technical challenge. The current practice of applying each product's individual rebates (specified in a

contract with a customer for the medications) to calculate its best price, clearly is the most appropriate from both a theoretical and technical perspective.

- *AMPs Use in Calculating 340B Pricing* – Per the letter dated January 30, 2007 from Jimmy Mitchell, Director of the Office of Pharmacy Affairs, the old (pre-DRA) methodology for calculating AMPs should continue to be used when calculating 340B ceiling prices. This would be a tremendous administrative burden to manufacturers to have to calculate two separate sets of AMPs each quarter under two different methodologies. Additionally, and perhaps more importantly, in many instances it would result in higher prices for 340B plan participants than if the new AMPs were utilized. Therefore, we strongly recommend that a technical correction to the 340B AMP definition be executed such that the AMP methodology used in 340B pricing is brought into sync with the newly defined Medicaid AMP methodology.

- *Hospital Sales* – The proposed regulation includes sales and discounts to hospital outpatient pharmacies in the calculation of AMP, but excludes those to inpatients. We recommend that both inpatient and outpatient sales be excluded from the AMP calculation due to the technical difficulties in securing separate data for these two sets of patients.

- *Patient Coupons* – We request that CMS confirm that a coupon should be considered redeemed directly by a patient to the manufacturer (and thus excludable from AMP/BP) when the manufacturer contracts with a vendor to administer the program, where the vendor otherwise is not a purchaser of the product. Coupons submitted by patients to pharmacies, who are subsequently reimbursed by the manufacturer for the coupon and handling costs, through a third party vendor, should be considered redeemed directly by the patient to the manufacturer.

- *Readjustment of ASP Threshold Percentage* – Under the ASP statute, if ASP exceeds by 5 percent the Widely Available Market Price (WAMP) or AMP, CMS may substitute the lesser of the WAMP or 103 percent of the AMP. The revised definition of AMP will significantly reduce AMPs in some cases, particularly because the revised definition of AMP includes discounts that are not included in ASP (e.g. Part D and SPAP discounts). This will increase the likelihood that AMP will be substituted for ASP, such that physicians will be reimbursed less than their acquisition cost. CMS should therefore increase the 5 percent threshold percentage.

- *Best Price Possible Submission* – We request clarification from CMS regarding the best price that is submitted with the initial submission after quarter's end. Currently manufacturers are directed to submit the best price based upon actual sales, rebate and discount data. If a manufacturer has a high degree of confidence that the total discounts offered for a particular NDC

will ultimately exceed 15.1 percent of AMP for the quarter, we would like to know if the manufacturer can submit an estimated best price for the initial submission to promote a more accurate initial submission as opposed to waiting until the final actual data is received before submitting the best price.

- *TRICARE* – The proposed rule states that TRICARE sales and discounts should not be included in the calculation of AMP, and further states these TRICARE sales are distributed via a "depot" process. The definition of depot, for purposes of VA/DOD pharmaceutical distribution via the retail TRICARE pharmacies, has not yet been established, and has been the subject of debate between manufacturers and the Department Veteran's Administration. We recommend that the classification of the retail TRICARE pharmacies as a depot should be avoided until such time when this has been resolved.