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February 16, 2007

FEB 20 2007

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

Re: File Code CMS-2238-P
Medicaid Program: Prescription Drugs

Dear Ms. Norwalk:

Medco Health Solutions, Inc., appreciates the opportunity to comment on the proposed rule implementing provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. Medco, a publicly held corporation, is a leading provider of managed prescription drug care, serving Fortune 500 companies and other employers, insurance and Blue Cross Blue Shield plans, state employee and retirement plans, health plans and other major sponsors of a prescription drug benefit. Working with these benefit plan clients, Medco Health manages the drug benefit for approximately 62 million Americans. Medco, through its insurance subsidiaries, is an approved Medicare Part D Prescription Drug Plan.

Medco is the nation's largest provider of prescriptions through mail service. Medco's twelve (12) state-of-the-art mail service pharmacies, located in eight states, dispensed approximately 82 million prescriptions last year to beneficiaries under the benefit plans we administer. Medco also operates comprehensive specialty pharmacies, through its subsidiary Accredo Health, Inc., that provide clinical support while dispensing drugs used to treat patients with complex, chronic conditions. The Medco mail service and Accredo specialty pharmacies dispense drugs on a national basis; each Medco and Accredo pharmacy has undertaken the necessary licensing, registration or other regulatory steps to enable dispensing prescription medications in its home state and into other states. In addition, Medco contracts to provide a network of more than 60,000 retail pharmacies nationwide.

Our comments focus on four issues raised by the proposed rule: the definition of retail pharmacy class of trade, classification of pharmacy benefit managers (PBMs) as wholesalers, including Medicare Part D pricing in AMP calculations, and recognition of

the unique status of specialty pharmacy. We offer our recommendations to assist CMS in its implementation of the DRA, in a manner consistent with congressional intent.

Background

The term “average manufacturer price” (AMP) was created by the Omnibus Reconciliation Act of 1990 (OBRA '90) as the basis for calculating the rebates to be paid by manufacturers to the Medicaid program. OBRA '90 defined AMP as manufacturer sales to wholesalers for the “retail pharmacy class of trade.” In 2006, the DRA adopted AMP, and rejected “average wholesale price” (AWP), as the new basis for reimbursing pharmacies for drugs subject to Medicaid Federal Upper Limit (FUL) requirements, namely generic products. By enacting the DRA, Congress expressed its intent to establish a new benchmark for the Medicaid program that accurately reflects what retail pharmacies actually pay wholesalers to acquire covered outpatient prescription drugs.

Determination of Average Manufacturer Price—Section 447.504

Definition of Retail Pharmacy Class of Trade and Determination of AMP (Federal Register, Vol. 71, No. 246, p. 77178)

We urge CMS to exclude mail service pharmacy prices and discounts, and PBM discounts, rebates and other price concessions, from the definition of “retail pharmacy class of trade” and from the calculation of AMP by manufacturers. To include them would lead to adoption of a new benchmark that could be as far from *actual prices* paid by retail pharmacies on the low side as AWP was from *actual prices* paid by retail pharmacies on the high side. Not only would this nullify Congressional intent in setting up the new benchmark, but it could undermine the current pharmacy distribution system and lead to cost-shifting to the private sector.

In the preamble to the proposed Rule, CMS states:

“While there is no requirement that States use AMPs to set payment amounts, we believe the Congress intended that States have drug pricing data *based on actual prices* (emphasis added), in contrast to previously available data that did not necessarily reflect actual manufacturer prices to the retail pharmacy class of trade.”

We strongly agree with this statement.

Unfortunately, the language of the proposed Rule would require manufacturers to include in their AMP calculations the “prices of sales and discounts to mail service pharmacies” and “PBM rebates and price concessions that adjust the amount received by the manufacturer for drugs distributed to the retail pharmacy class of trade.” Including mail and PBM pricing in AMP calculations are likely to artificially lower AMPs and produce inaccurate and unfair reimbursement rates.

Mail service pharmacy pricing should not be included in AMP because such pharmacies do not operate like a retail pharmacy, nor do they dispense to the general public. Mail service pharmacies are usually owned by or contract solely with a PBM or health plan. Access to the pharmacy is limited to individuals enrolled in a health plan, and the drugs dispensed are subject to plan-determined formularies, co-payments and exclusions. We

also note that mail service pharmacy has, historically, been of limited significance to state Medicaid programs, where virtually all prescriptions are dispensed by retail pharmacies.

Similarly, PBM drug pricing, including rebates, should not be included in AMP calculations because the pricing obtained by PBMs reflects the fact that market share can be driven by the PBM and the health plan sponsor through formulary status and placement, benefit design (e.g., tiered co-payments or closed formulary plan design), compliance monitoring, therapeutic interchange programs and physician education. Retail pharmacy does not have the same ability to influence manufacturer pricing and, accordingly, does not receive the benefit of such pricing and rebates.

If State Medicaid programs adopt AMP as the benchmark for *all* Medicaid pharmacy reimbursement -- which some states have indicated they are considering -- lower AMPs will decrease State payments to retail pharmacies across all drug classes and have significant impact to retail pharmacy's bottom line.

The Government Accountability Office (GAO) recently compared the AMPs of 77 drugs to the average pharmacy acquisition costs of those drugs and found that 59 of the 77 drugs had AMPs that were substantially less than pharmacy acquisition cost, even when the 250% multiplier was added. What's more, GAO used AMP data that did not reflect the proposed changes by CMS, such as inclusion of PBM and mail service pharmacy discounts and rebates. If GAO had used AMPs based on the proposed calculations, the AMP numbers would have been even lower.

State Medicaid reimbursement using a benchmark that reflects prices well below the actual acquisition costs for retail pharmacies could create dislocation in the market. On the one hand, it could lead to cost-shifting to the private sector. On the other, it could undermine the health of the retail sector. As a PBM, we rely on the independent and chain pharmacies in our retail networks to dispense prescriptions to the vast majority of the patients we serve. Government regulations that have a significant impact on retail pharmacy are of great concern to us and our clients.

For years, both private and public sector payors and PBMs have utilized maximum allowable cost (or "MAC") programs to determine adequate reimbursement rates for retail pharmacies for multi-source, generic drugs. The reason is "AWP" does not provide a meaningful gauge of the retail pharmacy's acquisition costs when several generic manufacturers are competing to produce the same drug. MAC programs generally employ empirical market data to arrive at reimbursement rates that cover acquisition costs and a reasonable margin, but do not take into account PBM mail pricing since it is not available to retail pharmacies. We respectfully suggest that including such pricing in the calculation of AMP would likewise give rise to inequitable and inaccurate results.

It is also a concern that the "retail class of trade" in Medicaid differs with the definition of retail pharmacy for Medicare Part D. The Medicare Part D drug benefit defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy." 42 C.F.R. Section 423.100. In Part D, CMS also recognizes that "home infusion pharmacies" are not "retail" pharmacies due to the "ongoing clinical monitoring, care coordination and

home infusion nursing that is provided by staff of or affiliated with the home infusion therapy provider.” 42 C.F.R. Section 423.100.

The Medicaid program should adopt a definition for retail pharmacy that is similar to and consistent with the Medicare Part D program. Two large federal health entitlement programs like Medicare and Medicaid should have compatible definitions for retail pharmacy. Inconsistency between these two programs will lead to confusion and burdensome administrative and recordkeeping requirements for drug manufacturers, health plans, wholesalers, and pharmacies. And, frankly, the Medicare Part D definitions are a more accurate reflection of what constitutes the “retail class of trade.”

Solicitation of Comments on PBMs acting as Wholesalers (Federal Register, Vol. 71, No. 246, p. 77179)

The preamble makes at least two references to PBMs acting as wholesalers and requests comment in the section discussing the definition of retail class of trade and calculation of AMP. CMS adopted a very broad definition of “wholesaler” in its drug manufacturer rebate agreement, which may be read to mean that any entity that buys prescription drug products from a manufacturer and does not relabel those products is a “wholesaler.” This definition does not align with other federal and State laws governing the licensure and regulation of drug wholesalers.

PBMs are not licensed as wholesalers. To the extent that they buy drugs directly from manufacturers, they do so as licensed pharmacies and the subsequent sale of those products to patients is pursuant to valid prescriptions executed by a health care professional with the legal authority to prescribe drugs. Drug wholesalers are not allowed by State or federal law to sell FDA approved drug products directly to patients.

Treatment of Medicare Part D Sales (Federal Register, Vol. 71, No. 246, p. 77180)

The Medicare Modernization Act (MMA) specifically exempts prices negotiated by Prescriptions Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs) from the calculation of Medicaid “best price” under section 1927. The proposed Rule would require manufacturers to include in their AMP calculations the prices of sales through a PDP, MA-PD, or a qualified retiree prescription drug plan for covered Part D drugs. Rebates paid to these payers are also required to be included in the calculation. Thus, while prices charged to Part D plans cannot create a new “best price” for the Medicaid program, including Part D prices that are lower than typical commercial prices in AMP calculations could further reduce the reported AMPs below the actual cost to retail pharmacies. As a matter of public policy, this result would be a windfall to the manufacturers and an additional burden for retail pharmacy.

Direct Patient Sales (Federal Register, Vol. 71, No. 246, p. 77180)

The direct distribution arrangement described on pages 77180-77181 is not how our specialty pharmacy subsidiary, Accredo Health Inc., purchases the drugs it dispenses to patients. The only time our specialty pharmacy subsidiary does not take title to drug products is when it administers a manufacturer assistance program for patients with financial need.

It is important for CMS to understand and recognize the characteristics of a specialty pharmacy. These characteristics differentiate specialty pharmacy from the “retail class of trade” that Congress had in mind when it enacted the DRA. Specialty pharmacies manage patients who:

- have complex diseases or conditions, many of which are rare diseases or conditions treated by products approved under the Orphan Drug Act of 1983 (P.L. 97-414)
- require sophisticated therapy management services and care coordination, including pharmacologic management, 24/7/365 access to a nurse or pharmacist with specialized training and experience pertaining to the patient’s condition,
- require extensive and ongoing coordination of care between the treating clinician and the specialty pharmacy,
- require special handling and delivery of prescribed medications,
- require customized administration through the use of ancillary providers and services,
- require approved medical waste disposal programs,
- require extensive, often onsite patient or care-giver training for medication administration and self-monitoring of their disease or condition,
- require ongoing therapy compliance monitoring, patient support, complication management, and intervention programs,
- require detailed performance reporting to minimize cost and maximize therapeutic outcomes.

The drugs prescribed to these patients are for complex chronic, terminal and/or rare conditions that affect a small percentage of the population. Such drugs typically cost more than \$6,000 per year for a course of therapy, and often have a short shelf life, special manufacturer handling requirements, and limited availability or distribution. These drugs seldom are carried in the inventory of retail pharmacies and typically are not available to be dispensed to retail pharmacy patients.

A patient is referred to a specialty pharmacy by his or her treating physician. Physicians direct patients to those specialty pharmacies that treat the specific medical condition diagnosed. Specialty pharmacies typically dispense prescriptions to the patient at home, either by mail or in conjunction with a home visit by a health professional.

Like long-term care pharmacies, specialty pharmacies serve a limited group of patients who require a level of professional services, compliance training, and clinical monitoring that is not available in retail pharmacy settings. Because specialty pharmacies limit their services to a defined population and do not “dispense to the general public,” we believe they should not be included in the definition of “retail pharmacy.”

Further, as states adopt reimbursement policies based on AMP, CMS should advise States to establish appropriate dispensing and service fees for specialty pharmacies. Such fees reflect the special handling and shipment required to deliver the product to the patient and the costs of providing the clinically necessary services such pharmacies provide to patients with complex, chronic, terminal and/or rare conditions. These services enable patients to stay at home, ensure the effectiveness of their treatment regimen, and ultimately reduce costs to the Medicaid program. Medicare has previously recognized the appropriateness of these add-on service payments with the hemophilia factor products

add-ons. While we recognize that the DRA does not specifically address these add-on service fees, we believe that commentary in the final rule which encourages states to support the payment of additional service fees is appropriate and will help ensure continued access to these necessary drugs for these fragile patients. The benefits provided by specialty pharmacy need to be addressed and appropriately reimbursed.

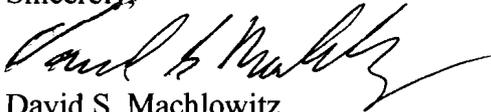
Summary and Conclusions

In summary, we recommend that the proposed Rule be modified to:

- exclude PBM and mail service pharmacy prices, discounts, rebates, and other price concessions from the calculation of a manufacturer's AMP;
- exclude prices charged to PDPs, MA-PDs and qualified retiree prescription drug plans for covered Part D drugs from the calculation of a manufacturer's AMP;
- recognize that PBMs are not licensed as wholesalers under state law and should not be so characterized for purposes of calculating AMPs for the Medicaid program, and
- recognize that specialty pharmacy should be treated the same as nursing home or long-term care pharmacies and should not be included in the definition of the "retail pharmacy class of trade."

Again, we appreciate this opportunity to comment on the proposed Rule and we welcome the opportunity to work with CMS on assuring the successful implementation of the DRA.

Sincerely,



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SVP, General Counsel & Secretary
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February 20, 2007

By Hand Delivery

Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 Attention: CMS-2238-P
 Room 445-G
 Hubert H. Humphrey Building
 200 Independence Avenue, SW
 Washington, DC 20201

FEB 20 2007

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

We appreciate this opportunity to submit comments on behalf of Together Rx Access, LLC with regard to the proposed rule implementing those provisions of the Deficit Reduction Act of 2005 ("DRA") relevant to the Medicaid Drug Rebate Program. 71 Fed. Reg. 77174 (Dec. 22, 2006) (the "Proposed Rule"). As you may know, Together Rx Access, LLC is comprised of pharmaceutical manufacturing companies which provide a prescription drug savings program at the point-of-sale to low-income, uninsured patients.¹ This program is called the Together Rx Access program.

Prior to the implementation of the DRA, Centers for Medicare and Medicaid Services ("CMS") Director Dennis G. Smith informed Together Rx Access, LLC in the attached April 22, 2005 letter ("April 2005 Letter") that CMS had concluded that the Together Rx Access program, as described in that letter, would not have implications for the determination of Best Price. The DRA amendments to the statutory definition of Best Price do not affect this conclusion; nor does the Proposed Rule.

Nonetheless, in light of the DRA amendments and the Proposed Rule, we strongly encourage CMS to confirm its April 22, 2005 conclusion with respect to the program. We ask that CMS confirm that a program that meets the following operational requirements continues not to implicate Best Price:

- 1) The program is focused on extending financial assistance to certain low-income individuals and families who are not otherwise eligible for Medicare and do not have public or private prescription drug coverage.
- 2) Each manufacturer establishes an amount of the subsidy to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or Pharmacy Benefit Manager (PBM)), as to that amount.

¹ The current members of Together Rx Access LLC are: Abbott Laboratories; AstraZeneca Pharmaceuticals LP; sanofi-aventis U.S. LLC; Bristol-Myers Squibb Company; SmithKline Beecham Corporation d/b/a GlaxoSmithKline; the pharmaceutical operating companies of the Johnson & Johnson family of companies; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Takeda Pharmaceuticals North America, Inc.; TAP Pharmaceutical Products Inc.

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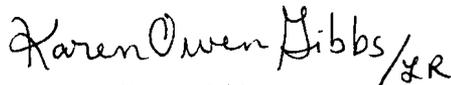
- 3) The entire amount of the subsidy is made available to the individual patient, without any opportunity for the retail pharmacy or any other third party (such as an insurer or PBM), to reduce that subsidy, or take a portion of it, for its own purposes.
- 4) The pharmacy reimbursement formula provides that the pharmacy will be reimbursed based in accordance with the formula set forth in the April 2005 Letter, and the pharmacy collects no additional payment, other than the subsidy amount, from the Together Rx Access program.

Because these four elements of the program, which Director Smith highlighted to us as the basis for CMS' prior determination, still hold true, and because the DRA amendments did not affect this conclusion, we request that CMS explicitly recognize that the Together Rx Access program does not implicate Best Price.

We request that CMS issue this explicit acknowledgement so as to encourage current and future industry support for this important program. Manufacturers participating in Together Rx Access, LLC have structured the subsidies offered through the program based on the assurance in the April 2005 Letter from CMS that the program will not affect Best Price. We fear that CMS's failure to acknowledge the continued inapplicability of the program for Best Price may discourage manufacturers from joining or participating in the program. By expressly excepting subsidies of this nature offered directly to patients, CMS will help to ensure that the Together Rx Access program continues to succeed in its mission of making prescription drugs affordable for low-income, uninsured patients.

Thank you for this opportunity to comment on the Proposed Rule. Of course, we would be happy to meet with you or CMS staff to discuss any questions or issues.

Sincerely,


Karen Owen Gibbs

Enclosure (April 2005 Letter)



Center for Medicaid and State Operations

APR 22 2005

Mr. John W. Treece
Sidley Austin Brown & Wood LLP
10 S. Dearborn Street
Chicago, IL 60603

Dear Mr. Treece:

Thank you for your letter presenting to us the revised methodology for the Together Rx Access savings program. The Centers for Medicare & Medicaid Services (CMS) appreciates the efforts of those manufacturers participating in the Together Rx Access to lower the cost of prescriptions for certain low-income individuals and families.

As we understand it, the Together Rx Access program operates as follows:

- The program is focused on extending pharmacy assistance to certain low-income individuals and families with incomes below 300 percent of the Federal Poverty Level, who are not otherwise eligible for Medicare and do not have public or private prescription drug coverage.
- Each manufacturer establishes an amount of the benefit to be given to individual patients, without any negotiation between the manufacturer and a third party (such as an insurer or Pharmacy Benefit Manager (PBM)), as to that amount.
- The entire amount of the benefit is made available to an individual patient, without any opportunity for the retail pharmacy or any other third party (such as an insurer or PBM), to reduce that benefit, or take a portion of it, for its own purposes.
- The pharmacy reimbursement formula provides that the pharmacy will be reimbursed based upon the lower of: (a) a formula "ceiling price" equal to AWP - 13 percent + \$2.00; or, (b) the pharmacy's usual and customary price for the drug. However, some retail outlets will have a slightly different formula to determine the total amount of the pharmacy charge to participants.
- The pharmacy collects no additional payment, other than the benefit amount, from the Together Rx Access program.

CMS believes that the drug prices in the Together Rx Access program described above would be exempt from best price under section 1927(c)(1)(C) of the Social Security Act.

Page 2 – Mr. John W. Treece

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

Sincerely,

A handwritten signature in cursive script, appearing to read "Dennis G. Smith".

Dennis G. Smith
Director



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February 20, 2007

By Hand Delivery

FEB 20 2007

Leslie V. Norwalk, Esquire
 Administrator
 Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 Attention: CMS-2238-P
 200 Independence Avenue, SW
 Washington, DC 20201

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

Dear Administrator Norwalk:

We greatly appreciate this opportunity to provide comments on the proposed rule implementing certain provisions of the Deficit Reduction Act of 2005 ("DRA") concerning the Medicaid Drug Rebate Program ("Proposed Rule").¹ Sidley Austin LLP ("Sidley") is a law firm consisting of over 1,700 attorneys across 14 domestic and international offices. We appreciate the opportunity to work closely and collaboratively with the Centers for Medicare & Medicaid Services ("CMS" or "Agency") and its dedicated personnel on a host of issues affecting the Medicaid program.

We thank the Agency for its significant and important efforts to simplify the calculations of Average Manufacturer Price ("AMP") and Best Price ("BP") and to articulate clearer guidance on a variety of price reporting issues that pharmaceutical manufacturers have struggled with in the past in the absence of specific guidance.

In this comment letter, we raise the following issues:

- PBM Price Concessions: We express our profound concern that the Proposed Rule is, in our view, being misinterpreted by a few industry analysts to suggest that the Proposed Rule obligates manufacturers to add price concessions provided to a pharmacy benefit manager ("PBM") to other concessions that may be provided to a PBM's customers, for Best Price purposes. Although we do not believe that the Proposed Rule can or should be read in this fashion, because such a proposal would contradict

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

the plain language of the Medicaid statute, we write to encourage CMS to clarify its position further.

- Prospective Application of the Final Rule: Consistent with what we believe to be the intent of the Proposed Rule, we strongly encourage CMS only to apply the Proposed Rule prospectively.
- Interim Final Rule with Comment Period: We urge CMS to issue an interim final rule with a comment period, in light of the ambiguity and confusion surrounding various aspects of the Proposed Rule. The issuance of an interim final rule with a comment period will allow CMS to address any concerns that arise in connection with its publication of a final rule.

I. Inclusion of Price Concessions to PBMs within Best Price Calculations

We agree with CMS that, by statute, Best Price is the lowest price made available “from the manufacturers...to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity [with certain exemptions].”² The statute has an unambiguous meaning, and CMS must give effect to the plain language of the statute.

However, in the limited context of PBM concessions, a few industry analysts have appeared to misread the Proposed Rule as suggesting that manufacturers may be obligated to add concessions paid to PBMs to the concessions paid to customers of the PBM in calculating Best Price. In our view, this misinterpretation of the Proposed Rule is flatly inconsistent with the statute. Best Price is **not**, by statute and by prior guidance, the lowest price available from a PBM in **its** pricing to **its** customers. The Medicaid statute requires that Best Price be the “lowest price available **from the manufacturer**,” not from a PBM or any other entity.³ There is no ambiguity on this point.

The misreading of Best Price that we address here is inconsistent with the statute, then, because it would effectively call for combining two separate prices, one offered to a PBM and the other offered to a customer of the PBM. The plain language of the statute does not permit such mixing and matching of separate prices. The statute is quite clear in defining Best Price as the lowest price to “**any** wholesaler, retailer, provider, health maintenance organization, non-profit entity, **or** governmental entity...”⁴ If Congress had intended anything other than a customer by customer analysis of separate prices, it would not have used the words it did. Rather than referring to each unique customer type separately, the statute would have combined them with the word “and,” instead of the disjunctive “or.”

² Proposed Rule, 71 Fed. Reg. at 77181, *referencing* 42 U.S.C. § 1396r-8(c)(1)(C) (2006).

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

⁴ *Id.*

We are confident that CMS has not proposed this misreading of Best Price. Indeed, a number of provisions in the Proposed Rule itself reveal that CMS is proposing a definition of Best Price that is consistent with the statute. Best Price, CMS states, is the lowest price “available from the manufacturers” reflecting concessions “provided by the manufacturers.”⁵ Accordingly, we are confident that CMS will adopt a definition of Best Price in the final rule that is consistent with the statute and that will not invite a legal challenge.

II. Final Rule’s Prospective Application

Although we discern no intent by CMS that the Proposed Rule should apply retrospectively, we write to underscore the importance that the Proposed Rule only apply prospectively, as retrospective application of the rule would pose significant legal and logistical problems.

In many respects, the Proposed Rule represents a significant modification to CMS’ current guidance that will fundamentally alter a variety of manufacturer practices related to AMP and BP calculations. To the extent that these changes adversely affect manufacturers, only prospective applications would be appropriate and consistent with the requirements of the Administrative Procedures Act (“APA”). In the past, pharmaceutical manufacturers have repeatedly been required to avail themselves of the reasonable assumption mechanism provided under the Medicaid Rebate Agreement because of the absence of clearer guidance on a variety of price reporting issues. The Proposed Rule discusses a number of areas of ambiguity that previously had been addressed by manufacturers through their reasonable assumptions. Retroactive application of a final rule would be inconsistent with the prior guidance regarding reasonable assumptions and would, effectively, punish manufacturers for making reasonable assumptions as directed by CMS.

Accordingly, retroactive application of a final rule would be inconsistent with the APA. The APA and the cases under that statute have required only prospective application of substantive changes in regulatory policy after notice and an opportunity for comment.⁶ We urge CMS to confirm its intent to apply the proposed provisions prospectively as required by the notice and comment requirements of the APA.

Manufacturers face daunting operational issues, even in implementing a final rule prospectively. Retrospective application would be substantially more difficult, and, we fear, impossible, in many cases. Manufacturers already struggle with price reporting calculations. If CMS required recalculations based on its newly proposed policy, manufacturers would often, in our view, be at a loss as to how to modify their current databases and information systems to

⁵ Proposed Rule, 71 Fed. Reg. at 77174.

⁶ *Coalition for Common Sense in Gov’t Procurement v. Sec’y of Dept. of Veterans Affairs*, 464 F.3d 1306, 1308-9 (Fed. Cir. 2006), citing *Paralyzed Veterans of America v. West*, 138 F.3d 1434, 1436 (Fed. Cir. 1998).

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comply with this mandate. Even if manufacturers were able to modify their databases and other related computer systems to meet CMS' demand for recalculations, this would impose an enormous operational challenge on manufacturers, and, we believe, CMS. Manufacturers and their customers, for instance, may simply not have collected the required set of data to submit revised calculations in compliance with the Proposed Rule's guidance.

For all of these reasons, we recommend that CMS expressly limit the final rule's application to future AMP and BP calculations.

III. Issuance of an Interim Final Rule with a Comment Period

Given the complexities surrounding AMP and BP calculations and the inevitable questions that will arise upon the issuance of a final rule, we fully support the issuance of an interim final rule with a comment period. There is significant confusion regarding the correct interpretation of a number of the proposals contained in the Proposed Rule. An additional comment period will allow CMS to more closely examine the impact of its guidance and make any adjustments that may be necessary after a final rule is issued. An interim final rule with an accompanying comment period will foster even greater dialogue between the pharmaceutical industry and CMS and further collaboration with the government.

IV. Conclusion

We applaud CMS for its much appreciated work in seeking to address more clearly some of the many complex issues surrounding the AMP and BP calculations.

Sincerely,



William A. Sarraille

11

The Specialty & Biotech Distributors Association
1501 K Street, NW
Washington, DC 20005

February 20, 2007

Hand Delivery

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-P
Room 445-G
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200 Independence Avenue, SW
Washington, DC 20201

FEB 20 2007

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

Dear Ms. Norwalk:

The Specialty and Biotech Distributors Association (“SBDA”) submits the following comments to the Centers for Medicare and Medicaid Services (“CMS” or “the Agency”) on the Proposed Rule: “CMS-2238-P: Medicaid Program; Prescription Drugs.” We appreciate the opportunity to discuss a number of important issues unique to specialty distributors. In our comments, we focus on issues related to bona fide service fees, the importance of excluding customary prompt pay discounts from both the definition of Average Manufacturer Price (“AMP”) and Best Price, and the need for further clarification regarding the definition of “retail class of trade” as it pertains to drugs administered within the physician office setting. While SBDA believes that drugs administered within a physician office setting should be excluded from the retail class of trade for reporting and reimbursement purposes, the Proposed Rule does not specifically denote this fact. Accordingly, we respectfully request that the Agency confirm our interpretation in the Final Rulemaking.

As CMS finalizes this rulemaking, we urge the Agency – to the extent feasible and permissible under the statute – to define the myriad of definitions impacting the Medicaid Program in a manner consistent with other federal health care programs. Following such an approach will increase compliance with all federal laws, and equally important, will minimize regulatory burdens and program complexities that may unintentionally establish an uneven playing field between competitors’ pharmaceutical products.

I. Background on SBDA

SBDA is comprised of companies dedicated to maintaining the integrity and efficiency of the specialty distribution system in physician offices and other settings. Much of our regulatory efforts have focused on obtaining clarifications to the Average Sales Price (“ASP”) system, but ensuring that AMP and Best Price are defined appropriately is also critical given the increasing number of physician-administered specialty drugs and biologics that are reimbursed under Medicaid.

Our members include AmerisourceBergen Specialty Group, Cardinal Health, Inc., Curascript, Health Coalition, Inc., Oncology Therapeutics Network, and U.S. Oncology. Together, we represent over eighty percent of the physician office specialty distribution volume in the United States.

Specialty distributors provide tremendous value and efficiency to federal health care programs. While often not visible to the public, specialty distributors manage the increasingly complex handling and delivery requirements of drugs and costly new biologics for virtually all physician offices in the country. These distributors perform important services, such as warehousing products, providing specialty handling and shipping services (such as packaging, refrigeration, or customized dosing), and ensuring the timely delivery of drugs and biologics to physicians and providers. Our specialty distributors typically do not sell drugs within the “retail class of trade,” so our comments focus on core issues that arise in this rulemaking regarding physician-administered drugs.

II. CMS’s Proposal to Exclude Bona Fide Service Fees from AMP Will Establish a Uniform and Consistent Treatment of these Fees Across the Medicare and Medicaid Programs

In the Proposed Rule, CMS clarifies that bona fide service fees should be excluded from the calculation of AMP. SBDA applauds the Agency for its position on this matter. The Proposed Rule defines 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 otherwise perform (or contract for) in the absence of the service arrangement, that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.” This language replicates the definition CMS recently finalized in the context of the ASP methodology for Medicare Part B Drugs in the CY 2007 Physician Fee Schedule Final Rule. 71 Fed. Reg. 69,624, 69,787 (Dec. 1, 2006).

SBDA strongly supports CMS’s proposed definition of bona fide service fees and believes the Agency’s decision to adopt the same definition of these fees for both ASP and AMP will enhance uniformity in reporting across the Medicare and Medicaid Programs. For distributors and manufacturers, establishing one consistent definition of bona fide service fees is essential to improving compliance and reducing administrative burden and complexity. As such, in finalizing this rulemaking, we encourage CMS to confirm several points by replicating portions of the narrative of the Physician Fee Schedule Final Rulemaking and deleting the specific reference to “distribution fees” in the Proposed Rule’s definitions of AMP and Best Price.

SBDA's request to reiterate the narrative of the Physician Fee Schedule Rulemaking is important, yet easy to implement. Specifically, we ask CMS to confirm that the terms "bona fide," "itemized," and "actually performed on behalf of the manufacturer or otherwise performed" include "any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." 71 Fed. Reg. at 69,668. The Agency developed this definition after receiving significant commentary regarding ASP from SBDA and many other interested parties. In that context, CMS recognized that the definition of bona fide service fees should not be restrictive as it might impede the development and innovation of specialty distribution services and practices. So long as a service provides "value" to a manufacturer, and meets the other prongs of the service fee test, the ASP Final Rulemaking permits exclusion of the related fee from the calculation of ASP.

For ease of reference, the Agency should simply repeat in the Final Rule the ASP narrative cited above pertaining to "value to the manufacturer that are associated with the efficient distribution of drugs." Further, CMS should reiterate that AMP will incorporate the ASP definition's reference to services that are performed "on behalf of" a manufacturer as including both those services that a manufacturer possesses the capacity to perform and those that only another entity can perform. *Id.*

In the Proposed Rule, the second prong of the bona fide service fee definition provides that an excluded fee must equal fair market value. CMS specifically requested comments on this issue of fair market value. In response to this request, we ask CMS to utilize the same approach it took in the ASP context. Under that interpretation, CMS defined these fees as "expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities." 71 Fed. Reg. at 69,669. Under an identical interpretation for AMP purposes, CMS should continue to permit manufacturers, depending on the circumstances and the nature of the services involved, to calculate the fair market value for a *set* of itemized bona fide services, rather than for each service individually. Moreover, as the method for determining fair market value may vary based on the terms of the contract at issue, CMS should refrain from requiring manufacturers to follow a particular method for evaluating whether a fee equals fair market value. *Id.* These positions are articulated at great length in the Final Physician Fee Schedule Rulemaking. *Id.*

The last prong of the bona fide service fee definition requires these fees to "not be passed on, in whole or in part, to a client or customer of an entity." We again urge CMS to replicate its interpretation of this clause in the ASP context for AMP. CMS indicated for ASP purposes that if a manufacturer has ascertained that a fee paid satisfies the requirements of the bona fide service fee definition, "then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of an entity." *Id.*

Finally, SBDA believes CMS should apply the definition of bona fide service fees to the term "distribution services." Incorporating the term "distribution services" into the definition of AMP does not reflect the fact that many core distribution services – such as packaging, shipping and handling – may meet the test of a bona fide service fee and may be appropriately excluded from AMP. We believe the ASP Final Rulemaking already has clearly articulated a standard for exclusion. As such, the AMP Final Rulemaking need not reference distribution services as *necessarily* distinct from bona fide services. While distribution services may not always meet

the three prong bona fide service fee test established under ASP, they certainly *may* meet the definition. Thus, categorically including these terms in AMP is inherently contradictory and may confuse manufacturers and distributors regarding the scope of the recently implemented ASP definition.

III. CMS Should Finalize Its Proposed Definition of Customary Prompt Pay Discounts in the Definition of AMP

In the Deficit Reduction Act of 2005 (“DRA”), Congress statutorily excluded from AMP “customary prompt pay discounts” provided to wholesalers, yet did not define this term. To implement the requirements of the DRA, CMS proposes to define the term “customary prompt pay discount” to mean “any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date.” We support this proposed definition and encourage CMS to finalize it exactly as written in the Proposed Rule.

Manufacturers offer prompt pay discounts to specialty distributors in most contracting arrangements to recognize the “time value” of money and to reflect the credit risks associated with the management and delivery of drugs and biologics to physician offices. These contracting terms substantially lower the cost of distribution to the manufacturer and the physician and provide an incentive to distributors to make timely payments, which enhances the efficiencies within the supply chain to the benefit of patients, physicians, and the Medicaid Program.

The language of the Proposed Rule reflects Congress’ intent to exclude a broad and varied array of prompt pay dating terms. In fact, during the legislative debate, efforts were made to cap or limit the scope of these terms, but Congress rejected these initiatives. Congress wished to provide contracting flexibility to manufacturers and distributors because it was concerned about impairing the integrity of the supply chain or adding cost inefficiencies to the Medicaid Program. We urge CMS to reject similar efforts to limit these terms in the Final Rulemaking.

SBDA notes that the Proposed Rule specifically includes cash discounts in the calculation of AMP. While we believe CMS’s intent to exclude customary prompt pay discounts is clear, cash discounts in the pharmaceutical industry are sometimes expressed as “prompt pay discounts.” As such, when the Agency finalizes this rulemaking, we ask that it refrain from defining “cash discounts” in a manner that is inconsistent with the definition of customary prompt pay discounts in the Proposed Rule. Clarity and consistency of pricing terms is essential for the accurate submission of AMP data.

In these comments, we also wish to point out a potential inconsistency within the Department of Health and Human Services (“HHS”) regarding the new definition of AMP. Currently, the Health Resources and Services Administration (“HRSA”) is proposing to disregard the DRA-mandated prompt pay discount change to AMP for purposes of calculating 340B prices. As you know, the 340B statute uses the definition of AMP in the Medicaid statute as the foundation for 340B prices. In a January 30, 2007 letter to manufacturers, HRSA stated that for 340B price calculation purposes, manufacturers should continue to reduce AMP by the prompt pay discount despite the statutory mandate from the DRA. In effect, HRSA is requiring

manufacturers to produce two separate AMPs – one for use in the Medicaid program and one for use in the 340B program.

We fundamentally disagree with HRSA's regulatory authority to issue such a mandate and raise it to your attention. HRSA's suggestion to report a 340B-specific AMP is inconsistent with HRSA's past interpretation of the 340B statute and arguably constitutes an arbitrary and capricious exercise of regulatory authority because it will be at odds with the express terms of the DRA.

As supporting evidence for dual AMPs, HRSA cites a clause in the 340B statute (which exists within the Public Health Service Act) that indicates references in the statute to the Social Security Act should be read as those references existed when the 340B statute was created on November 4, 1992. The 340B statute contains ten references to the Social Security Act, the definition of AMP among them. The substance of many of these references has changed significantly since November 4, 1992, and, up until now, HRSA has readily incorporated these changes into the functioning of the 340B program. To now require the definition of AMP for 340B purposes to be the same as the definition in effect on November 4, 1992 would not only be unduly burdensome for manufacturers, but would set a dangerous and ill-advised precedent for future changes.

Given that the statutory underpinnings of the 340B program are so closely intertwined with the Medicaid program, we believe coordination and consistency between CMS and HRSA is vital to the success of both programs. To the extent manufacturers, covered entities, and others in the supply distribution chain must manage both programs using common definitions and interlocking policies, HHS should encourage consistency between the agencies. Accordingly, HHS should require HRSA and CMS to utilize the same definition of AMP for Medicaid and 340B purposes. Prompt payment terms should be excluded from both programs.

IV. CMS's Proposal to Exclude Bona Fide Service Fees From Best Price Ensures Uniformity of Treatment of these Fees in Medicaid; a Similar Approach Should be Adopted for Prompt Pay Discounts

Unlike its proposals in the AMP context, CMS proposes to *include* customary prompt pay discounts in the calculation of Best Price, despite the fact that these terms are not intended to serve as price concessions and “do not affect the price actually realized by the manufacturer.” For a number of important public policy reasons, we urge CMS to modify its position in the Final Rulemaking and to exclude customary prompt pay discounts for purposes of Best Price in a consistent manner as it does for AMP. This approach more appropriately reflects the intent of Congress to continue encouraging the use of prompt pay discounting terms in contracts between manufacturers and distributors because they serve an important role in providing a revenue stream to distributors to ensure the safe and effective distribution of drugs to patients.

In the Proposed Rule, CMS argues that no evidence exists to suggest that Congress intended to change the definition of Best Price to exclude customary prompt pay discounts. While it is true that the DRA did not directly amend this provision, characterizing Congress' intent on this position as unclear is incorrect. Congress' express purpose in excluding customary prompt discounts from AMP was to eliminate any incentives to limit the use of these terms.

Congress' objective may only be accomplished if CMS treats these terms in a consistent manner for AMP *and* Best Price.

Further, the fact that customary prompt pay discounts typically do not represent price concessions and do not “affect the price actually realized by the manufacturer” is another important reason for CMS to exclude customary prompt pay discounts from the Best Price determination.

The historic treatment of price concessions in the determination of Best Price is noted clearly throughout CMS guidance on the definition of Best Price. Significantly, the Agency's guidance documents indicate that pricing terms should be included only when they “affect the price actually realized by the manufacturer.” Here, CMS may appropriately exclude customary prompt pay discounts on those grounds even though the DRA did not modify the statutory section of Best Price. No statutory change is required to reflect the Agency's long-standing policy of including in Best Price only those pricing terms that represent price concessions.

Finally, we note that the Proposed Rulemaking treats bona fide service fees in a consistent manner for AMP and Best Price. We applaud this approach because it confirms that bona fide service fees do not constitute price concessions. CMS should exclude customary prompt pay discounts from Best Price for that same reason.

V. Scope of the “Retail Class of Trade Definition” As It Applies to Physician-Administered Drugs

We commend CMS for proposing to define the “retail pharmacy class of trade” to ensure that manufacturers determine AMPs in a more consistent manner, but we are concerned with the ambiguous manner in which the Proposed Rulemaking applies the definition to the physician office class of trade. We urge CMS to explicitly state in the Final Rule that the retail class of trade does not include physician-administered drugs.

Section 1927(k)(1) of the Social Security Act, which governs the Medicaid Rebate Program, defines AMP to mean, “with respect to a covered outpatient drug of a manufacturer for a rebate period, 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, after deducting customary prompt pay discounts.” Section 1927(k)(1), Social Security Act (emphasis added). Until the issuance of the Proposed Rule, the Medicaid Program has operated without a clear or consistent definition of the entities included in and excluded from the retail class of trade. As CMS explains in the preamble to the Proposed Rule, both the Government Accountability Office (“GAO”) and the Office of Inspector General (“OIG”) expressed concern regarding the inconsistencies in manufacturers' methods for determining AMP and, as a result, recommended that CMS define the phrase “retail pharmacy class of trade.”

Ambiguities in the Preamble

To respond to the GAO's and OIG's concerns, CMS proposes in the preamble to the Proposed Rule to define the retail pharmacy class of trade to include “any entity that purchases prescription drugs from a manufacturer or wholesaler for dispensing to the general public . . .

except as otherwise specified by statute or regulation (such as, HMOs, hospitals).” (emphasis added). In reaching this definition, CMS explains in the preamble to the Proposed Rule that it considered broad definitions, which would encompass prices to nursing home facilities, and narrow definitions, which would exclude prices to pharmacy benefit managers (“PBMs”) and other entities. In the end, CMS decided upon a definition that it believes is broad enough to remain consistent with past guidance and avoids resulting in a higher AMP. Moreover, CMS appears to have focused narrowly on whether an entity dispenses drugs to the general public – instead of whether it is traditionally viewed as a “retail” outfit – as a key factor in separating those entities included in the retail class of trade from those that are excluded. For example, it considered including prices of sales to nursing home pharmacies (long-term care (“LTC”) pharmacies), but ultimately excluded them because they do not dispense drugs to the general public.

Nowhere in the preamble does CMS specifically state whether it intends to include prices to physicians in the retail class of trade. In the same way that CMS excluded sales to LTC pharmacies from the AMP calculation because they typically are closed operations that serve only residents of a specific LTC facility, a physician office is not a retail location open to the general public. Unlike a retail pharmacy, a physician office is a closed operation that does not permit patients to purchase prescriptions on a walk-in basis. No one can dispute the fact that these drugs are not available to the general public. Individuals are permitted to purchase drugs from a physician’s office only if they are patients of that physician. Further, the range of drugs that may be purchased in a physician’s office are restricted to those drugs that the physician administers or dispenses and patients may not obtain drugs under a prescription from another physician. Accordingly, CMS should adopt a “general public” test that excludes drugs administered in the physician office setting from the retail class of trade.

At the same time, however, CMS does intend to calculate AMPs for purposes of determining rebates owed under the Medicaid Program. Thus, CMS is left with an inherent inconsistency in terms of how to apply the AMP rule to physician-administered drugs. On the one hand, CMS must facilitate the collection of rebates. On the other hand, CMS must breathe meaning into the definition of retail class of trade and “general public.”

SBDA would suggest that CMS resolve this tension by calculating the AMPs for purposes of determining rebates owed to the Medicaid Program, but employing a separate system for purposes of public reporting and reimbursement. Failure to take such an approach would, in some cases, artificially lower the AMP reimbursement levels substantially enough that many retail pharmacies might be unable to purchase certain drugs for an amount under the Medicaid reimbursement levels.

The Agency must reconcile the two conflicting provisions of “retail class of trade” and the terms that should be included in AMP for purposes of calculating rebates. As CMS considers this issue, we note that although Congress took action in the DRA to amend the Medicaid statute to require the submission of data on physician-administered drugs for the purpose of determining Medicaid *rebates*, it chose not to amend the statute’s treatment of physician-administered drugs for *reimbursement* purposes. Moreover, the Proposed Rule even makes explicit mention of the fact that, to implement the requirements of the DRA, it must consider physician-administered

drugs to be covered outpatient drugs for the “limited purposes of determining rebates on these drugs.” (emphasis added). This indication acknowledges CMS’s understanding that for all purposes other than determining rebates, physician-administered drugs do not constitute covered outpatient drugs within Medicaid.

For all of these reasons, we respectfully request that the Agency modify its approach to sales that will be used for purposes of calculating reimbursement and public reporting.

VI. Conclusion

SBDA appreciates the opportunity to submit comments to CMS on significant matters affecting the integrity and financial viability of the specialty distribution system. We urge the Agency to finalize this rulemaking in a manner that recognizes the importance of consistent and uniform treatment of bona fide service fees and customary prompt pay discounts across the Medicaid Program. We further ask the Agency to confirm our interpretation of the scope of the definition of AMP. While the statutory language is potentially inconsistent, it does not envision including physician-administered drugs in the retail class of trade for reimbursement and reporting purposes.

Respectfully Submitted,



John F. Akscin
President
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February 20, 2007

FEB 20 2007

VIA HAND DELIVERY AND ELECTRONIC DELIVERY

The Hon. Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-2238-P, Proposed Rule – Medicaid Program, Prescription Drugs

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services (“CMS”) proposed rule on Medicaid Program, Prescription Drugs, the “Proposed Rule”.¹ Daiichi Sankyo, Inc. respectfully submits the following comments to the Proposed Rule regarding Medicaid average manufacturer price (“AMP”) and Best Price (“BP”) calculations. We appreciate the opportunity to submit these comments and are available to discuss them with you at your convenience.

We understand the challenges associated with providing clear guidance with respect to the highly complex issues surrounding the AMP and BP calculations. As a general matter, we are concerned that the Proposed Rule raises several questions that, if unanswered, may lead to inconsistencies in manufacturers’ price reporting. We have set forth some of these issues below for your consideration. Where possible, we have attempted to organize our comments pursuant to the headings in the Proposed Rule.

I. DAIICHI SANKYO, INC. BACKGROUND

Daiichi Sankyo, Inc. is headquartered in Parsippany, New Jersey, and is the U.S. subsidiary of Daiichi Sankyo Co., Ltd., a global pharmaceutical company headquartered in Japan. The company’s strategic focus is on cardiovascular diseases. Research and development of new therapies is also focused in the areas of glucose metabolic disorders, infectious diseases, cancer, immunology and bone and joint diseases. Daiichi Sankyo’s portfolio of covered outpatient drugs currently includes Benicar® (olmesartan medoxomil) and BenicarHCT® (olmesartan medoxomil/hydrochlorothiazide), WelChol® (colesevelam HCl), Evoxac® (cevimeline HCl) and Floxin OTIC® (ofloxacin otic).

II. GENERAL COMMENTS

We respectfully request that CMS define what the terms “include” and “exclude” mean with respect to the dollars and units components of the AMP calculation generally. The Proposed Rule is not clear as to how to treat such terms for purposes of actually performing the AMP calculation. For example, if a discount is

¹ 71 Fed Reg. 50,428 (Dec. 22, 2006), file code CMS-2238-P.

“included” in AMP, does CMS expect manufacturers to deduct the value of the discount from the numerator (dollars) of the AMP equation but keep associated units in the denominator (units)? Similarly, for an “excluded” sale, are the dollars to be subtracted out of the numerator and not reduced by any related discounts, and the associated units to be subtracted from the denominator? If so, in cases where the purchase price associated with an “excluded” sale is not known to the manufacturer (as is often the case with indirect sales), how should a manufacturer value such units – at wholesale acquisition cost (“WAC”)? Alternatively, should “excluded” transactions be ignored (e.g., neither sales dollars, discounts or units deducted from the AMP calculation) in light of the difficulties in valuing the sales? Is there a difference in the treatment of transactions that are “not included” versus transactions that are “excluded”? In some cases the Proposed Rule references including “sales” to certain entities, in some cases it references including “sales and associated rebates, discounts and other price concessions”: does CMS intend there to be a difference in the affect on sales dollars, discounts and units based on the terminology used? In this regard, we request that CMS include both of the following in the final rule: (i) a sample AMP calculation and (ii) a chart indicating for each of the various entities that may affect the AMP and BP calculation whether sales, discounts, and/or units are deducted from the gross ex-factory dollar and unit numbers for purpose of calculating AMP.

III. SPECIFIC COMMENTS

A. Section 447.502 (Definitions)

1. Bona Fide Service Fees

- a. The Proposed Rule states that service and administrative fees are included in AMP. However, the Proposed Rule states that “bona fide” service fees are excluded from AMP, without reference to administrative fees. Can an administrative fee qualify as a “bona fide service fee” that would be excluded from AMP?
- b. If an administrative fee is paid to a group purchasing organization in accordance with the group purchasing organization statutory exception and/or safe harbor to the federal healthcare anti-kickback statute (21 C.F.R. § 1001.952(j)), does it also need to fit the definition of “bona fide service fee” to be excluded from AMP?
- c. When defining the term “bona fide service fees” for purposes of the average sales price (“ASP”) final rule issued on December 1, 2006, CMS included extensive guidance in the preamble interpreting the various components of this term (*see* 71 Fed. Reg. 69623, 69666-70 (Dec. 1, 2006)). We respectfully request clarification as to whether CMS’s guidance on this term issued in the ASP context is relevant to the analysis of service fees in the AMP and BP context. Specifically, we respectfully request CMS to clarify that, as is the case with ASP: “If a manufacturer has determined that a fee paid meets the other elements of the definition of ‘bona fide service fee,’ then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.”
- d. We respectfully request clarification that service and administrative fees, regardless of whether such fees are “bona fide” as defined by CMS, are not “included” in AMP unless paid to an entity included in AMP under Section 447.504(g) of the Proposed Rule. Also, if a service fee is determined not to be “bona fide”, should manufacturers prorate the service fee to apportion it to AMP-included sales only? Because AMP-excluded sales are removed from gross sales, the discounts associated with such sales should be removed from the gross discount dollars before the discounts/rebates being included (dollars being removed) from AMP calculations. Otherwise, it would result in an artificially low AMP number and this AMP number would reflect sales to AMP-included entities and discounts for AMP-included and AMP-excluded entities.

2. Bundled Sale

- a. "Bundling" is defined under the Proposed Rule to include an arrangement where an "other price concession is conditioned upon the purchase of the same drug or drugs of different types..." Does CMS mean to state that a bundle is where the discount on one drug is contingent upon the purchase of another drug (i.e., discount of drug X is contingent upon the purchase of drug Y)? While we do not believe it is the intention of CMS to consider different strengths of the same drug (e.g., same NDA, different NDCs) being offered to a customer as being a bundle, we believe that the definition requires clarification.

B. Section 447.504 (Determination of AMP)

1. (a) AMP means...

- a. As a general comment, while some wholesalers may send a manufacturer detailed reporting as to each entity to which they have sold the manufacturer's product, this is not necessarily a standard for all wholesalers and all manufacturers. As such, manufacturers in many cases rely on chargeback data to identify the retail pharmacy class of trade for AMP calculations. To the extent there is no chargeback associated with a sale, a manufacturer may have no way of knowing whether the end purchaser was "retail". We are seeking confirmation from CMS that this is acceptable.

2. (c) Customary Prompt Pay Discount means...

- a. We respectfully request clarification of the meaning of the word "routinely" when defining customary prompt pay discounts. If a manufacturer offers special or extended terms on a limited basis (e.g., during product launch) would such discounts be considered "routine" and, if, so, how should a manufacturer account for them with respect to AMP and Prompt Pay Discount reporting?

3. (e) Retail Pharmacy Class of Trade means...

- a. The Proposed Rule defines the "Retail Pharmacy Class of Trade" to include a pharmacy benefit manager (or "PBM"). We interpret the Proposed Rule to treat both PBM mail order business as well as other PBM business as retail pharmacy class of trade. If this interpretation is correct, it is logical that CMS should also treat non-staff model managed care organizations and employer group health plans as retail pharmacy class of trade. When a PBM is acting in a mail-order capacity as the rebate contracting agent of a plan, the financial incentives are analogous in many ways to a plan performing its own rebate contracting, and it seems incongruous to treat these two arrangements differently. We seek clarification in this regard.

4. (f) Wholesaler means...

- a. The definition of "wholesaler" appears to be inconsistent with CMS's list of sales included in the AMP calculation under the Proposed Rule. Because the AMP is to reflect the average price "from wholesalers for drugs distributed to the retail pharmacy class of trade" (emphasis added), CMS may need to adjust the definition of "wholesaler" to incorporate some of the entities listed under Proposed Rule § 447.504(g) such as individual patients (see §447.504(g)(7)). Alternatively, we respectfully suggest that CMS reconsider whether all of the sales enumerated under §447.504(g) are appropriately "included" in AMP based on the proposed definition of "wholesaler".

5. Sales, Rebates, Discounts, or other Price Concessions included in AMP

- a. We note that Proposed Rule § 447.504(4) states that nominal price sales to a “covered entity described in section 340B(a)(4) of the Public Health Service Act” are not included in AMP. Under the Deficit Reduction Act of 2005 (Pub. L. 109-171 (Feb. 8, 2006), the Medicaid Drug Rebate Statute at 42 U.S.C. 1396r-8(a)(5)(B) was amended to include certain children’s hospitals in the definition of “covered entity” for purposes of the Best Price exclusion. However, the definition of “covered entity” under Public Health Service Act was not amended accordingly. Will prices to such children’s hospitals (defined in 42 U.S.C. § 1396r-8(a)(5)(B)) be eligible for the AMP exclusion?
- b. We respectfully request clarification as to CMS’s position on PBM price concessions. In the preamble, CMS states: “We propose to include any rebates, discounts or other price adjustments provided by the manufacturer to the PBM that affect the net price recognized the manufacturer for drugs provided to entities in the retail pharmacy class of trade.” Is it CMS’s intent, based on its inclusion of PBMs in the definition of “retail pharmacy class of trade”, that all rebates, discounts or other price adjustments to PBMs be included in (deducted from) AMP, unless specifically excluded? Alternatively, does the language “that affect the net price recognized by the manufacturer for drugs provided to entities in the retail pharmacy class of trade” place a burden on manufacturers to trace any non-mail order PBM discounts to the ultimate seller to identify whether such seller is an entity in the retail pharmacy class of trade? In the mail order context, chargeback data will generally allow manufacturers to attribute PBM discounts to the ultimate seller of the product. However, in non-mail order arrangements, where the PBM is not a purchaser, there can be difficulties in tracing and classifying such end sales. In many cases, such classification will be impossible. We respectfully request clarification as to CMS’s expectations in this regard.
- c. We request that CMS add the wording “where identifiable and to the extent the data is available” when giving guidance on what items to include or exclude from AMP calculations (e.g., discounts given to an excluded class of trade that cannot be identified in a rebate submission from a PBM).
- d. Section 447.504(7) of the Proposed Rule “includes” direct sales to patients. See the discussion above under regarding the definition of “wholesaler.” We note that “including” these sales and presumably, discounts, in the AMP calculation may potentially serve as a disincentive for manufacturers to offer patients assistance programs or other subsidies to patients. If the intent of the AMP calculations is to determine the net price by wholesalers to the retail class of trade, including sales and discounts directly to patients may improperly lower the AMP.
- e. Section 447.504(10) of the Proposed Rule “includes”: “rebates, discounts, or other price concessions (other than rebates under Section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade.” We respectfully request that CMS clarify the meaning of the term: “associated with”.
- f. The Proposed Rule states that only manufacturer coupons redeemed directly by the patient can be excluded from AMP and BP:
 - i. We note that manufacturer coupons and vouchers, directly or indirectly redeemed by the patient, serve to provide financial assistance to patients rather than the “retail pharmacy class of trade.” We note that as an administrative matter, manufacturers do not always process patient coupons and vouchers directly. Two scenarios are common: (i) a patient will pay a co-pay for the

product at the pharmacy and then redeem a coupon to a third-party vendor under contract with the manufacturer, and the vendor (not the consumer) will then invoice the manufacturer for the value of the coupon; (ii) a patient will present with a coupon or voucher at the pharmacy, and the pharmacy will supply the drug to the patient out of its inventory, at a reduced cost to the patient according to the terms of the coupon, and the vendor (not the consumer) will then invoice the manufacturer for the reimbursement paid to the pharmacy (which may include a negotiated rate and a dispense fee). Is it CMS's intent that the value of coupons or vouchers redeemed by third party vendors are to be "included" in AMP and BP calculations? We respectfully request that they should not be, in light of the negligible impact such arrangements have at the "retail" pharmacy level versus the tremendous benefit to patients.

- ii. If CMS determines to include coupons and vouchers in AMP and BP, we respectfully request that CMS provide guidance on how to value such transactions for purposes of the respective calculations. For privacy reasons, manufacturers often do not have full transparency into the dispensing of a coupon or voucher prescription (e.g., how many tablets are dispensed with a particular coupon). Similarly, even if the manufacturer were to have such transparency, other valuation issues should be addressed (e.g., if a single coupon were redeemed for an order of product that has to be filled over two prescriptions due to a pharmacy not having the full amount of medication to dispense at once – how should such coupon be allocated?).
 - iii. If CMS determines to include coupons and vouchers in AMP and BP, we respectfully request that CMS provide guidance regarding how a manufacturer may properly structure a Patient Assistance Program utilizing coupons (if the coupons are redeemed either at the pharmacy or through an agent of the manufacturer) and still keep its patient assistance program BP and AMP exempt.
 - iv. We respectfully request that CMS define "coupon" and clarify its position with respect to vouchers including the characteristics of a voucher program versus a coupon program.
- g. Section 447.504(12) of the Proposed Rule "includes": "sales and associated rebates, discounts, or other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program (MA-PD), State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), and Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under Section 1927 of the Act or as otherwise specified in the statute or regulations)." We respectfully request that CMS clarify the meaning of the term: "associated with sales of drugs provided to the retail pharmacy class of trade". If a manufacturer were to provide discount to a PBM in connection with its Medicare Part D mail order business, would that discount be "included" in AMP? We further request that CMS clarify the handling of a qualified retiree prescription drug plans for purposes of AMP.
- h. We respectfully request that CMS clarify the meaning of the following statement in the preamble of the Proposed Rule: "Therefore, we would clarify that rebates paid to the States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that the price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included." This will also effect SCHIP XIX. How are rebates paid to states Medicaid agencies under either the CMS Rebate Agreement or a CMS-approved supplemental rebate agreement (and the associated units) to be

treated for purposes of AMP? Are manufacturers expected to perform some level of diligence to "trace" Medicaid sales to the retail pharmacy class of trade.

6. (h) Sales, Rebates, Discounts, or other Price Concessions excluded from AMP

- a. We respectfully request confirmation that clearly identifiable indirect sales to "excluded" entities should be excluded from AMP calculations (e.g., sales identified through chargeback data). Similarly, please confirm that indirect sales to excluded entities, if not identifiable as such by the data available to a manufacturer, are not required to be "excluded".
- b. We respectfully request that CMS clarify whether the references to health maintenance organizations ("HMOs") and managed care organizations ("MCOs") under section 447.504(h)(5) of the Proposed Rule are limited to so-called "staff-model" HMOs and MCOs that purchase pharmaceuticals for dispensing to their members, or whether they include so-called "IPA-model" HMOs and MCOs that arrange for pharmacy discounts but do not actually purchase drugs.
- c. We respectfully request clarification as to the appropriate AMP treatment of direct and clearly identifiable indirect sales and discounts to entities that dispense to only their own patients (e.g., to physicians, home health care, clinics, long term care, prisons, ambulatory care centers, surgi-centers, and other outpatient health care centers).
- d. We respectfully request clarification as to the appropriate AMP treatment of discounts and administrative fees paid to group purchasing organizations.
- e. We support CMS's determination to exclude returned goods from the AMP calculation. However, we respectfully request additional clarification regarding what it means that goods were "returned in good faith." Assuming that a manufacturer has no evidence to the contrary, may a manufacturer assume that goods are returned in good faith? Alternatively, we request that CMS delete the "good faith" requirement, as this issue is in the purview of the returners and not the manufacturer.
- f. We request clarification on whether a manufacturer may treat all chargeback reversals as returns if data is not available to the manufacturer to indicate otherwise.

7. (i) Further Clarification of AMP Calculation

- a. We understand that the requirement that a manufacturer must adjust the AMP if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized is not new. However, we suggest that CMS consider implementing a tolerance level for quarterly AMP variation, within which an AMP restatement (positive or negative) would not be permitted, in order to reduce the burden on states, CMS and manufacturers.
- b. When calculating quarterly AMP, would CMS consider allowing manufacturers the option of calculating a weighted quarterly AMP based upon the monthly AMPs that were submitted for the quarter? In this regard, we would respectfully request that manufacturers choosing this option not be required to restate AMPs. This would eliminate restating of quarterly AMPs as monthly AMPs are generally not allowed to be restated. This would also reduce the administrative burden on the states, CMS and manufacturers in connection with the restatement of quarterly AMPs.

C. 447.505 (Determination of Best Price)

1. CMS states for Best Price reporting “that the best price includes the lowest price available to any entity...” We respectfully request that CMS clarify that the intent of this provision is that the BP represents the best price *achieved* and consider conforming the proposed regulation to this intent.
2. When referencing “Tricare” after depot throughout the Proposed Rule is CMS stating that all Tricare discounts (mail and retail) are to be excluded from AMP and best price? Further, if CMS is asserting that Tricare’s retail discount program (TrXX) is viewed as a depot, we respectfully request that CMS clarify that CMS is interpreting only the Medicaid Drug Rebate Statute and not the Veterans Health Care Act.
3. With regard to a manufacturer’s patient assistance program (“PAP”), would reduced charges to recipients be included in best price? The Proposed Rule indicates that only “goods provided free of charge under a manufacturers’ patient assistance program” would be exempt. We respectfully request that CMS exclude all prices under manufacturer PAPs from BP determinations.
4. The determination of what constitutes a “state pharmaceutical assistance program” (“SPAP”) has been subject to varying guidance from CMS over the years. We are familiar with the several CMS Manufacturer Releases in this regard. We respectfully request that this issue be resolved through the regulatory process. One suggestion would be that manufacturers be allowed to rely on the most current SPAP list published by CMS, and that any deletions from that list apply only prospectively from the first date a manufacturer is able to terminate its contract with that program.
5. See also comments above under AMP discussion.

D. Section 447.506 (Authorized Generic Drugs)

1. The Proposed Rule indicates that, with respect to authorized generics, the original manufacturer must include the authorized generics’ manufacturer’s data in the calculation of AMP and Best Price. In light of the potentially anticompetitive ramifications of such data sharing, we respectfully request that CMS address an appropriate mechanism to exchange such information within applicable regulatory parameters, including those of the Federal Trade Commission.
2. We request that CMS clarify how manufacturers should handle situations where pricing data is not available from the secondary manufacturer.
3. We request that CMS clarify how manufacturers should account for any transfer pricing of the product when sold from the NDA-holder to the authorized generic manufacturer.
4. We request that CMS clarify that “authorized generic drugs” do not include situations where a drug product is purchased from a branded manufacturer and being marketed under two labeler codes solely during the term while the original product holder sells out its inventory.

E. Section 447.508 (Exclusion from Best Price of Certain Sales at Nominal Price)

1. We note that Proposed Rule § 447.508(a) states that nominal price sales to a “covered entity described in section 340B(a)(4) of the PHSA” are excluded from BP. Under the Deficit Reduction Act of 2005 (Pub. L. 109-171 (Feb. 8, 2006), the Medicaid Drug Rebate Statute at 42 U.S.C. 1396r-8(a)(5)(B) was amended to include certain children’s hospitals in the definition of “covered

entity” for purposes of the Best Price exclusion. However, the definition of “covered entity” under Public Health Service Act was not amended accordingly.

2. Separately, 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I) (and Section 447.505(d)(1) of the Proposed Rule) excludes any price to a “covered entity described in subsection (a)(5)(B) of this section (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title).”
3. Will nominal prices to children’s hospitals defined in 42 U.S.C. § 1396r-8(a)(5)(B) be eligible for the BP exclusion? Will such prices be separately reportable under Section 447.510(4) of the proposed rule?

F. Section 447.510 (Requirements for Manufacturers)

1. (a) Quarterly Reports

- a. Can CMS clarify how manufacturers will be required to report the Customary Prompt Payment discount to the agency from an operational perspective? For example:
 - When reporting customary prompt payment discounts, should manufacturers recognize these at the time of the sale of the product to the customer?
 - Do manufacturers report customary prompt payment discounts at the 9 digit NDC, the 11 digit NDC or at the labeler code level?

2. (c) Base Date AMP Report

- a. Due to the intense amount of resources that may be required to restate Base Date AMPs, we respectfully request that CMS offer additional time to complete this process beyond the first full quarter after the final rule has been published. We recommend that manufacturers be given 12 months to accomplish this. It may be difficult and, in some cases impossible, for manufacturers to recalculate Base Date AMPs, due to factors such as the passage of time and product sales and acquisitions. As an alternative to recalculating Base Date AMP, we respectfully request that CMS consider allowing manufacturers to calculate AMP under their current (pre-final AMP rule) methodology, then calculate AMP under the methodology established in compliance with the final AMP rule, when issued. The manufacturer could then use the ratio from that difference and apply it to their original Baseline AMP.

3. (d) Monthly AMP

- a. With respect to price concessions to the retail class of trade, is it acceptable for manufacturers to run monthly reports, and include these sales and discounts in the AMP calculations, based upon the “post” date of chargebacks, which indicates when a chargeback has been “paid”? This would be using the “cash” methodology.
- b. We respectfully request that CMS clarify how a manufacturer may “estimate” their monthly AMP. With respect to using an “estimation” or “smoothing” methodology, we recommend that manufacturers should be permitted to use a four-quarter rolling average of rebates to sales, and apply that percentage to monthly sales. Using a four quarter rolling average for smoothing is operationally more feasible than a 12-month rolling average because rebates and other price concessions are typically invoiced by customers and paid by manufacturer on a quarterly basis. We also request that CMS clarify that manufacturers should be allowed to estimate excluded sales for the month, using a four-quarter rolling average based upon gross

sales units divided by excludable AMP units for determining the ratio of non-eligible AMP sales.

- c. The Proposed Rule requests comment on the issue of estimating the lagged discounts associated with quarterly AMPs in addition to monthly AMPs. We note that in some cases, it may be appropriate for a manufacturer to use the estimation methodology for the monthly calculations and the cash methodology for the quarterly submissions, as, on a quarterly basis, the lagged concessions may be significantly reduced. We note that this may vary from manufacturer to manufacturer, and thus it would make sense for CMS to permit manufacturers to use either cash or estimation for quarterly AMPs, provided the determination as to which method is to be used is consistent.
 - d. Regardless of CMS's determination as to timeframe for estimation, we request that CMS clarify whether the current reporting period is included in the estimation (e.g., does the current month data count as one of the twelve months in a twelve-month rolling average?).
 - e. We respectfully request that CMS clarify how a manufacturer should treat a negative monthly AMP.
 - f. We respectfully request that CMS clarify what it considers to be "lagged price concessions".
 - g. CMS Manufacturer Release # 76 (Dec. 15, 2006) states: "Adjustments, such as those resulting from sales data, received after the reporting period ends, should be reflected in the next monthly AMP submission." We respectfully request that CMS confirm whether this is CMS's position under the Proposed Rule as well. If so, we note that the addition of data attributable to a previous month's transactions into a later month's AMP could artificially inflate or deflate the later month's AMP.
4. (e) Certification of Pricing Reports
- a. The requirement in the Proposed Rule that the CEO, CFO or delegated direct report of CEO or CFO certify the AMP and BP submissions seems unnecessary and burdensome to manufacturers. We note that there are already a number of significant legal disincentives to a manufacturer in connection with reporting inaccurate numbers, including civil monetary penalties and various state and federal prohibitions against false claims. As a practical matter, it may be difficult to obtain a signature from such senior executives on a routine basis every month, due to travel schedules. Moreover, such individuals are not necessarily in the best position organizationally to verify the accuracy of the reporting to CMS. Therefore, we respectfully request that CMS reconsider requiring such certification.
 - b. In the event that CMS keeps the certification requirement, we note that the references in the Proposed Rule to the CEO, CFO or delegated direct report of CEO or CFO may not fit the organizational structure of all manufacturers. The titles "CEO" and "CFO" are organization-specific, and we note that Daiichi Sankyo, Inc. has neither (rather, we have a President and a Vice President of Finance). We recommend that CMS clarify that the certification may come from an individual within the organization with authority and accountability equivalent to an individual holding such a title.

G. Other Comments

1. We note that there is a strong potential for duplicate discounting by manufacturers in connection with physician-administered drugs that are paid as primary under Medicare and secondary under Medicaid. In some cases, this could result in a manufacturer being required to rebate more than

100% of the WAC of a product on a single claim. We respectfully request that CMS use this rulemaking as an opportunity to clarify that when a state Medicaid program pays on a drug claim in the capacity of a secondary payor, such Medicaid program should not be entitled to a full rebate on the associated unit. We do not believe that it was the intent of the Medicaid Drug Rebate Statute to permit states to claim rebates that are disproportionate to the reimbursement payments made by the states on the drugs.

2. How should manufacturers handle the Health Resources and Services Administration Office of Pharmacy Affairs' ("OPA's") request for a separate AMP calculation (reduced by prompt pay discounts)? How would the OPA AMP number be reported to CMS (if OPA's request stands) so that CMS can use this AMP for their reporting obligations to OPA? This requirement may be burdensome for both manufacturers and for CMS.
3. What is the process for manufactures to dispute a monthly AMP published on the CMS website if they believe it to be incorrect?
4. Will manufacturers be permitted or required to restate their AMP back through 1Q2007 after the AMP rules become final? We respectfully request that CMS clarify that any final rule applies prospectively only. In this regard, we further request that CMS permit manufacturers at least six months from the publication of the final rule to be in compliance with any requirements that are not statutory requirements under the Deficit Reduction Act of 2005.

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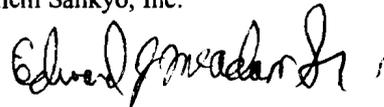
Leslie Norwalk
February 20, 2007
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Please feel free to contact us if you have any questions or require further information in this regard.

Sincerely,

Daiichi Sankyo, Inc.

By:



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February 20, 2007

Rec'd FEB 20 2007 *EB*

BY HAND DELIVERY

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

Re: Comments of Allergan, Inc., Forest Laboratories, Inc., Otsuka America
Pharmaceutical, Inc., and Reliant Pharmaceuticals, Inc. on Proposed
Rule CMS-2238-P, Medicaid Program Prescription Drugs

Dear Sirs:

The following comments to the Centers for Medicare and Medicaid Services (CMS) are submitted on behalf of Allergan, Inc. of Irvine, California, Forest Laboratories, Inc. of New York, New York, Otsuka America Pharmaceutical, Inc. of Rockville, Maryland, and Reliant Pharmaceuticals, Inc. of Liberty Corner, New Jersey, in response to CMS' proposed rule to implement provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program, which was published in the Federal Register on December 22, 2006 (71 Fed. Reg. 77174-77200). Allergan, Forest, Otsuka, and Reliant are manufacturers of single source and innovator multiple source drugs, as defined in section 1927(k) of the Social Security Act, and all participate in the Medicaid rebate program. We welcome this opportunity to address the specific proposals in the proposed rule affecting the methodology by which the Average Manufacturer Price (AMP) and best price are calculated and reported to CMS.

The following comments are organized by topics addressed in the proposed rule. In the first section, the subject of the comment is limited to the calculation and reporting of AMP. In the second section, the subject pertains to the treatment of particular transactions as price concessions in both AMP and best price. The third section concerns the calculation and reporting of best price and other pricing data submitted to CMS.

As a preliminary matter, CMS must reassess the small business impact of the proposed rule. CMS estimates that the majority of the 550 manufacturers affected by the rule are small businesses, yet its limited assessment of the cost impact of the proposed rule on small businesses and manufacturers generally is inadequate. At this stage, it is difficult to determine whether rebate liability will be increased due to changes to the calculation of AMP and best price; however, such an increase is likely should the final rule alter the statutory definition of best price to require aggregation of separate discounts to distinct and unrelated entities if the discounts are "associated with" the same unit of a product. In addition, the preamble to the proposed rule grossly underestimates its impact in terms of the strain it will place on manufacturers' available resources and the administrative cost of implementation. The preamble estimates each of the manufacturers will spend \$50,000 on start-up costs and nothing additional for operations. In reality, companies must spend hundreds of thousands of dollars modifying their drug price reporting systems and hire additional personnel in order to meet the requirements of the proposed rule. The proposed rule must adopt reasonable policies that will be the least burdensome for manufacturers to implement. Specific operational issues and the impact from changes to best price are discussed below.

I. AMP – §447.504

Section 447.504(a) of the proposed rule would alter the statutory definition of AMP, which is "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," to the average price "received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade." We believe this change, coupled with the very broad definition of wholesaler, is intended to capture transactions with entities who do not pay manufacturers, directly or through distributors, a price established by the manufacturer. As discussed below, when combined with the proposed inclusions and exclusions from the calculation of AMP, this definition creates confusion as applied to pharmacy benefit managers that do not purchase or take delivery of product, and their client health plans that pay pharmacies for prescriptions dispensed to the plan members. It also creates confusion with respect to fees paid to group purchasing organizations which arrange for purchase prices paid by other entities but are not themselves purchasers and are not listed in the itemized transactions included in AMP.

A. Definition of Wholesaler – §447.504(f)

Section 447.504(f) of the proposed rule would define “wholesaler” as any entity that does not relabel or repackage the covered outpatient drug. No reference is made to whether the exclusion is limited to situations in which the entity relabels or repackages under the purchaser’s NDC. Section 447.504(g)(2) would include in AMP sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser’s NDC. We interpret the definition of wholesaler to mean it is exclusive of any entity that purchases a covered outpatient drug and repackages or relabels using the purchaser’s own NDC. Please confirm or provide guidance on what is meant for an entity to relabel or repackage under 337.504(f).

B. Retail Pharmacy Class of Trade – §447.504(e); Specific Inclusions and Exclusions §447.504(g),(h)

1. Definition/Entities Not Specified in the Rule: Section 447.504(e) of the proposed rule defines the “retail pharmacy class of trade” as any “outlet that purchases or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sell or provides the drugs to the general public.” As defined, this definition could apply to any health care provider that pays for drugs or uses them to treat a patient. In the preamble, the reason given for excluding institutional pharmacies in nursing homes and long term care facilities is that these pharmacies dispense drugs only to residents of the facilities, not the general public. Likewise, it appears that sales to HMOs and managed care organizations (MCOs) are excluded because they make prescription drugs available only to their members. Guidance is required as to what is meant by the “general public” in order to determine whether entities not specified in the rule fall within the “retail pharmacy class of trade.”

Sections 447.504(g) and (h) of the proposed rule list categories of customers and transactions that should be included or excluded from the calculation. However, the list is incomplete. Clarification is needed as to the treatment of private physician offices, surgical centers, ambulatory care centers, prisons, and mental health centers. Unlike walk-in pharmacies, these providers generally provide drugs incident to providing medical services to persons who are their private patients, although some physician practices sell self-administered products to patients who take the products home. We also note the proposed rule includes sales to “outpatient clinics” in AMP, but it is unclear if this reference is intended to capture pharmacies in physician clinics that dispense prescriptions (like hospital pharmacies) or drugs used by such clinics in the treatment of their patients. In addition, neither the list of included nor the list of excluded transactions references sales to home health care companies that deliver product to patients. Please clarify whether prices paid by home health care organizations for drugs delivered to home bound patients are included in AMP. Also, please explain how drugs distributed directly to patients fall within the definition of drugs distributed to the

retail pharmacy class of trade when patients do not resell or provide drugs to the general public

2. Hospital Pharmacies. Section 447.504(g) of the proposed rule includes sales to hospitals “where the drug is used in the outpatient pharmacy. Section 447.504(h) excludes sales to hospitals “where the drug is used in the inpatient setting.” As a policy matter, we have no objection to including in the retail pharmacy class of trade walk-in pharmacies located in hospitals. However, as an administrative matter, compliance with this rule will be very difficult. Most hospitals currently buy for their inpatient and outpatient requirements from their regular wholesaler or distributor under agreements negotiated by group purchasing organizations. These agreements do not specify how the drugs will be used by the member hospital and chargeback data from wholesalers indicates only eligibility to purchase under the GPO contract. Although 340B hospitals maintain separate accounts for inpatient and outpatient use, and purchases under the 340B program are identified separately from purchases under a GPO agreement, there is no feasible way at present to determine how a drug is used by a regular non-340B hospital under a GPO agreement and thus whether it should be classified retail or non-retail. We suggest that manufacturers be permitted to assume hospital purchases are for their inpatient inventory and excluded from AMP unless sales to hospital pharmacies are identifiable.

It is also unclear whether the term “outpatient clinic” is intended to capture hospital surgical centers, ambulatory care centers and outpatient departments in which a patient is admitted to the hospital and released the same day. Even if a hospital has a separate pharmacy account, drugs purchased under a GPO agreement for use by the outpatient department in treating patients are typically included in inpatient inventory and cannot be identified at the point of sale as purchased for inpatient use or use by an outpatient department. Moreover, this distinction is an artificial one, as a drug provided to a patient of the hospital during an outpatient procedure is not provided to the general public any more than if provided during inpatient care. To avoid compliance problems and administrative burden, the final rule should make it clear that hospital purchases of drugs administered to their patients, whether on an inpatient or outpatient basis, should be treated the same.

3. Veterinary Offices: Sales to veterinary offices are not addressed in Section 447.504(g) of the proposed rule. Please clarify whether drugs approved for human use that are sold to veterinary offices for treatment of animals are considered sales to an entity that provides drugs to the general public, and thus fall within the definition of the retail pharmacy class of trade. In our view, veterinary offices are not licensed to provide drugs to people and thus could not provide them to the general public.

4. HMOs, MCOs, PBMs: Section 447.504(h) of the proposed rule excludes sales to health maintenance organizations (HMOs) including managed care organizations (MCOs), but defines neither. At the same time, Section 447.504(g) includes pharmacy

benefit managers (PBMs). In the pharmaceutical industry, an MCO is considered any organized health plan that provides a pharmacy benefit and manages the benefit cost through use of a prescription drug formulary. HMOs are a type of MCO. Some purchase and dispense drugs and provide mail order coverage, while others cover prescriptions filled by network pharmacies and mail order. MCOs use either captive or independent PBMs to manage the pharmacy benefit, including the negotiation of rebates that offset the prescription prices paid by the MCO. It is unclear whether the HMO/MCO exclusion from AMP applies only to purchases by MCOs that have their own facilities, or whether it excludes rebate transactions with health plans that reimburse network providers.

If rebates to HMOs/MCOs are to be excluded, it would be very difficult for a manufacturer to distinguish between a PBM transaction and a sale to an MCO, particularly when the PBM owns the mail order pharmacy filling the prescription purchased by the MCO. An independent PBM may include ERISA plans and other clients in addition to MCO clients, and the utilization data provided to manufacturers is not broken down by the type of entity. In addition, agreements with PBMs vary. Some agree to pass through rebates to their client plans and some do not, so that the amount of the rebate passed through to the plans depends on the arrangement between the PBM and its clients. In calculating monthly and quarterly AMP based on thousands of transactions, it is vital that companies be able to automate their systems. Automation requires bright lines and categorical treatment of transactions. Currently, companies treat PBMs and MCOs (other than staff model HMOs with their own facilities) as the same class of trade. A rule that would require monthly analysis of PBM agreements to assess their relationship with MCOs in order to determine whether a rebate is in or out of AMP, and then recode the transactions, would consume enormous resources and overly burden smaller manufacturers. It is imperative that manufacturers be able to comply with AMP in the least burdensome manner consistent with the availability of data and capabilities of drug price reporting systems. Accordingly, only transactions with clearly identifiable HMOs and health plans should be treated as excluded from AMP. Manufacturers must be able to treat rebates paid to PBMs that manage benefits for MCOs (as well as other clients) as "PBM rebates," whether or not passed through to MCOs.

5. Depot Prices (including Tricare) The proposed rule would exclude from AMP and best price depot prices to the federal government, including Tricare. The Tricare program purchases drugs through depot arrangements and also reimburses private sector retail pharmacies for prescriptions dispensed to Tricare beneficiaries. In its calculation of Non-Federal Average Manufacturer Price, the VA distinguishes between rebates paid on "depot" transactions, which it believes are mandated by statute, and which are currently not available to the Tricare program, and voluntary rebates paid on Tricare retail utilization which are not mandated by statute. The final rule needs to clarify whether this exclusion for depot prices applies both to mandatory rebates and voluntary rebates paid to DoD. If voluntary rebates paid to DoD are to be excluded, the

final rule must specify whether the units are to be left in the calculation, as with Medicaid rebates, or, if the units are to be excluded, the value at which the excluded units should be removed from the AMP calculation.

6. Medicaid Purchases. Section 447.504(g)(10) of the proposed rule would include rebates except rebates paid to Medicaid under section 1927 of the Social Security Act. Likewise, Section 447.504(g)(12) would include sales and associated rebates under Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade except rebates paid under section 1927 of the Act. The preamble to the proposed rule indicates this exclusion applies to supplemental rebates paid to the states as well. Please confirm and provide guidance as to whether this exclusion also applies when rebates are paid to Medicaid as a secondary payer under this title and the rebate agreement on outpatient prescription drugs covered by Medicare. Also, please explain what sales and associated rebates are paid under the Medicaid program other than those paid under section 1927 of the Act.

B. Restated Base Date AMP – §447.510

Section 447.510 of the proposed rule would require manufacturers to submit a Base Date AMP for the first full quarter following publication of the final rule. It would also permit manufacturers to submit a recalculated Base Date AMP. As proposed, however, the rule is inadequate. First, there is insufficient time to implement a recalculated Base Date AMP, particularly if manufacturers must use historical transactional data. Second, it must clearly account for statutory changes to AMP.

In their Medicaid rebate agreement, manufacturers agreed to pay the states a unit rebate amount on a covered drug comprised of a base rebate and an additional rebate penalty. The additional rebate is determined by the increase in current period AMP over the CPIU rate from the Base Date AMP. Prior to the DRA, Base Date AMP had to include Customary Prompt Pay (CPP) discounts routinely granted wholesalers, typically 2% of gross sales. The DRA specified that manufacturers must exclude CPP from AMP and report it separately. In discussions with industry prior to publication of the proposed rule, CMS acknowledged the need to provide an opportunity to adjust the Base Date AMP to reflect this and other statutory changes mandated by the DRA which could unfairly create the appearance of a price increase in excess of CPIU. In the product data reporting form sent to manufacturers and the instructions to industry, CMS provided a simple solution to the automatic – and artificial – increase created by the post-DRA exclusion of CPP from reported AMP: recalculate Base Date AMP to remove CPP and report a new DRA Base Date AMP that would be used to determine the additional rebate penalty after the DRA effective date. However, CMS subsequently reversed itself and prohibited manufacturers from reporting a restated Base Date AMP at this time.

The preamble to the proposed rule explains the intent is to allow manufacturers an opportunity to restate Base Date AMP so that the additional rebate penalty would not increase due to changes in the definition of AMP." However, the proposed rule appears to permit recalculation based on changes occurring only as a result of Section 447.504(e), the regulation defining the retail pharmacy class of trade. As written, it does not seem to permit manufacturers to restate the Base Date to account for all the changes to the definition of AMP, including the new requirement to exclude CPP and certain nominal prices. Changes resulting from reclassification of transactions as retail or non-retail may have no impact or may be impossible to apply to the baseline period, and in any event, do not adjust for the exclusion of CPP. Accordingly, a manufacturer must be able to restate the Base Date AMP, effective January 1, 2007, if it so chooses, to reflect statutory changes to the definition of AMP, whether or not it can recalculate transactions with customers based on changes to their categorization as retail or non-retail, in order to prevent wrongful application of the inflation penalty in the absence of an actual price increase. Moreover, manufacturers must have the discretion to calculate the adjustment for CPP based on the method used to include it (e.g., 2% of direct sales). We urge CMS to permit recalculation of the Base Date AMP due to statutory changes in the definition of AMP under Section 447.504(a). Failure to permit such an adjustment followed by application of the inflation penalty could be considered a breach of the rebate agreement.

C. Smoothing Lagged Discounts and Indirect Sales

1. **Lagged Discounts**. In its final rule on the calculation of ASP, CMS required manufacturers to use a specified "smoothing" formula for reducing gross sales by discounts on non-exempt sales based on actual historic data where the discounts lagged behind the sale to which the discount applied.. CMS' formula applies a percentage of gross sales over the prior four quarters against current quarter sales net of exempt sales. Similarly, the VA has, since inception of its program under the Veterans Health Care Act, permitted use of a formula to smooth chargebacks in calculating the Non-Federal Average Manufacturer Price (NFAMP) in order to reduce volatility in quarterly pricing. Currently, AMP can fluctuate considerably quarter to quarter. As AMP is used prospectively to calculate ceiling prices under the 340B program, those prices can also be volatile, creating budgeting problems for entities purchasing under the program.

We believe smoothing lagged discounts is beneficial when an average price is used for pricing purposes, because it is not feasible to adjust the basis for payment retroactively when lagged discounts applicable to sales in the quarter become known. Thus, the final rule should provide that a manufacturer opting to use a smoothing methodology for lagged discounts should be accompanied by a rule that the manufacturer need not retroactively adjust quarterly prices. However, we believe manufacturers should have a choice in using a smoothing technique or an estimation method based on accruals and sales experience, particularly with respect to monthly

AMP. In addition, even if a manufacturer opts to use estimates in the calculation of monthly AMP, it is too burdensome to require prior period adjustments to those calculations. We support the proposed rule prohibition against restatement of monthly AMP. Finally, smoothing should not be required for the first partial year of sales for new products because the Base Date AMP can be skewed by non-recurring post-launch start-up payments.

2. Lagged Indirect Exempt Sales: The proposed rule would neither require nor permit manufacturers to smooth units of indirect sales known in a period after the initial sale, as did the rule for calculating ASP. In our view, application of a smoothing process to indirect exempt units may be beneficial when there are variations in the volume of rebates paid to exempt entities. However, under the proposed rule, prescription units that are reimbursed by Medicaid or state supplemental Medicaid units would not to be removed from AMP and rebates to all other state and federal plans, such as Medicare Part D, would be included in the calculation. Therefore, we see no need at this time to address this issue. In the event CMS changes the proposed treatment of these transactions, discretionary smoothing of the units and removal of a corresponding value from gross sales dollars might be appropriate.

II. Treatment of Specific Transactions

A. Administrative Fees and Service Fees – §§447.504(h)(11); 447.505(d)(12)

Unlike the “safe harbor” regulations of the Department of Health and Human Services, the proposed rule does not differentiate between administrative fees paid to entities, such as group purchasing organizations and pharmacy benefit managers, who are not themselves purchasers but use the combined buying power of their members or client plans to negotiate prices and administer contracts on their behalf, and fees for other services, such as distribution and inventory management. The proposed rule would exclude both types of fees from AMP and best price if they satisfy the criteria for itemized bona fide services performed on behalf of a manufacturer for fair market value not passed through to a customer or client of the recipient, regardless of whether it takes title to the drugs. We support this exclusion because such fees are necessary business expenditures related to the efficient distribution of drugs and are not price concessions, even if paid to a wholesaler or other entity that has taken title to the drugs. However, we urge CMS to allow categorical exclusion of administrative fees of 3% or less if they fall within the GPO administrative fee safe harbor, including its limitation on ownership of members. Such a categorical exclusion would be consistent with the purpose of the statutory exemption and safe harbor, which encourage group purchasing arrangements, and alleviate the necessity to evaluate each GPO agreement to determine if it is fair market value for bona fide services received by the manufacturer.

In the preamble to the proposed rule, CMS acknowledges that it is adopting the same definition of service fee included in the final rule for ASP (December 1, 2006, 71 Fed. Reg. 69623-70274). As with the ASP rule, the proposed rule does not specify uniform standards for determining fair market value or list bona fide service. We agree with this approach. However, guidance is needed in interpreting these terms, and, unlike the preamble to the ASP rule, the preamble to the proposed Medicaid rule does not provide the same guidance on application of the criteria in the definition of service fee. For example, we believe manufacturers must have the discretion to decide whether a particular service is one useful to or needed by the manufacturer. The ASP final rule provides that a service is bona fide if it encompasses any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs, and further clarifies that a service performed on behalf of a manufacturer includes both those the manufacturer has the capacity to perform and those that can only be performed through another entity. 71 Fed. Reg. 69668. With respect to the determination of fair market value, we believe manufacturers should have the discretion to decide whether the fee for a service is fair and reasonable in light of industry-accepted practices and other factors, even if expressed as a percentage of the purchase price, and that a fee should be able to cover multiple, itemized services. In finalizing the ASP final rule, CMS agreed. It stated that "bona fide service fees means expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities," and that the appropriate method for determining FMV may depend on the contracting terms, such as the activities to be performed and the mechanism for establishing payment such as percentage of the purchase. 71 Fed. Reg. 69668-9. In addition, when warranted, FMV may be calculated as a single fee for a set of itemized services rather than FMV for each individual itemized service. 71 Fed. Reg. 69669. We also believe the treatment accorded a service fee should not depend on whether the company's books account for the fee as a reduction in cost of sales for financial reporting purposes. Again, for purposes of ASP. *Id.*

Finally, in the ASP rulemaking process, of particular concern to manufacturers was whether a payment of dividends or similar profit-sharing with members or other arrangements to which manufacturers are not privy would be considered a pass through of fees, if the fee was not intended to be passed on. We believe such fees should be excluded from all price calculations if there is no direct correlation between the fee paid and a distribution by the recipient. Moreover, manufacturers cannot ascertain whether a fee is passed on to a customer or client of the recipient. In response to such concerns, and in recognition that manufacturers may have no effective way of knowing whether a fee is passed on, the preamble to the ASP rule reasonably states that if a manufacturer has determined that a fee paid meets the other elements of the definition of bona fide service fee, it may presume the fee is not passed on to a client or customer in the absence of notice or evidence to the contrary. *Id.*

We urge CMS to include in the final Medicaid price reporting rule the same guidance provided in the preamble to the ASP final rule, or expressly incorporate that guidance by reference.

B. Authorized Generics – §447.506

The statutory provisions for treatment of sales of authorized generics are very confusing. In the proposed rule, CMS proposes that the owner of the drug's NDA combine the average price of the drug sold by the authorized seller to the retail pharmacy class of trade with the AMP for the brand. We support an interpretation that would permit the owner of the NDA to calculate a weighted average using the authorized seller's AMP and units (as CMS does with ASP) without having to obtain and combine all of the authorized seller's transactional data, because it would relieve some of the administrative burden of reporting a combined monthly AMP as well as reducing antitrust concerns in the case of unaffiliated licensees.

Likewise, the proposed rule would require the owner of the NDA to include in its best price the lowest price available from the authorized seller to any manufacturer, wholesaler, retailer, provider, etc., but does not require inclusion of the transaction transferring the drug to the authorized seller. We strongly support this interpretation as consistent with the statutory intent. It would mean the transaction included in best price would correspond with the transaction included in AMP – to the extent the sale was to an entity within the retail pharmacy class of trade. More importantly, it would not differentiate between sales of a drug by the owner of the NDA through a division, licensee, or reseller, and would be consistent with the treatment currently applied to sales by a co-promoter of the brand. Including the transfer transaction between the owner of the NDA and the authorized seller would be extremely difficult to administer because the labeler usually sources the drug through an interdivisional transfer, or, in the case of a licensee, by paying the manufacturing cost plus a royalty on the resale, not a purchase price.

The proposed rule does not address the situation in which the owner of the NDA does not sell the drug, but licenses the right to sell exclusively to another manufacturer that sells under its own NDC – often under a brand name. In our view, this situation is not contemplated by the statute and, as a practical matter, the owner of the NDA could not report a price as it has no NDC of its own. Indeed, because the owner of the NDA is not a source of the drug, the licensed drug would meet the definition of single source drug. Please confirm our interpretation is correct. The proposed rule also states that the authorized seller is to continue to report AMP and best price as it always has based on its own sales. However, in the event the licensee sells both a brand and generic version of the licensed innovator drug, clarification is needed as to whether the licensee, who is not the owner of the NDA, must combine the sales of its two NDCs in its own price reporting or continue to report separately as usual.

Last, clarification is needed that the AMP used as the benchmark for determining nominal price (for purposes of the AMP and best price exclusion) is the reported AMP, which means the combined AMP for the brand manufacturer.

C. Consumer Coupons – §§447.504(g)(11); 447.505(c)(12)

There is a fundamental flaw in CMS' proposal to include consumer coupons redeemed by a pharmacy in AMP and best price. Discounts to consumers off the prescription price charged by a pharmacy should not be included in the average price paid by [or received from] wholesalers for drugs distributed to the retail pharmacy class of trade, because such a discount is not an adjustment to the price paid by or received from the dispensing pharmacy or any other reseller of the drug. The benefit flows solely to the consumer. If a pharmacy is willing to accept a coupon as partial payment for the prescription, its expectation is to be made whole and receive the same retail price it would have without the coupon. While the consumer pays less for the prescription, the amount the pharmacy paid for the dispensed drugs is unaffected. The proposed rule's differing treatment based on whether the consumer redeems the coupon directly or through the pharmacy at the point of sale is an artificial one. In both situations, the consumer pays less than the price charged by the pharmacy and the manufacturer realizes less profit because of its partial payment of the consumer's prescription, but the pharmacy purchase price remains the same. The proposed rule does not indicate whether a payment made to a pharmacy on behalf of a consumer at the point of sale through a debit card provided by the manufacturer is a redemption by the consumer. However, it should not make any difference. Whether the consumer is paid directly by the manufacturer, or the manufacturer pays the pharmacy on behalf of the consumer, the beneficiary of the manufacturer's payment is the consumer not the retail pharmacy.

Paying the pharmacy a portion of a consumer's prescription through a debit card or reimbursing the pharmacy on behalf of the consumer in cash or replacement drugs should also not trigger a best price. First, a coupon represents a discount off the retail prescription price paid by a consumer, and, to the extent the undiscounted prescription price could be determined, the value of the coupon is only available to the consumer, which is not a wholesaler, retailer, provider or other "entity" within the statutory definition of best price. Second, the payment to the pharmacy on behalf of the consumer does not reduce the purchase price available from the manufacturer to the dispensing pharmacy or the wholesaler that sold the drug to the pharmacy. Third, as noted, there is no difference between a coupon redemption at the point of sale and a redemption by the consumer using proof of purchase, in terms of the price available to the pharmacy, the price available to the consumer, and the net amount realized by the manufacturer.

It is simply bad policy to include consumer coupons in best price, because it will result in consumers paying higher prescription prices. Coupons redeemed at the point of sale provide relief to uninsured consumers and help defray high co-pays for insured consumers. If reimbursing a pharmacy the value of a redeemed coupon must be

treated as a reduction in the price available to the pharmacy, manufacturers will be forced to either abandon the practice or to provide consumer discounts only through coupons redeemed directly by the consumer. Most coupons, however, are only redeemed if presented at the point of sale because of the length of time it takes to process the claim. More importantly, states are beginning to enact laws that require coupon redemption at the point of sale. Thus, if only manufacturer coupons redeemed directly by consumers are excluded from best price, consumers are unlikely to realize prescription cost savings available through coupons.

Finally, the proposed rule should clarify that coupons for free drugs, such as starter prescriptions, that are not contingent on the purchase of the same or any other drugs, should not be included in AMP or best price. These starter prescriptions (typically a week to a month supply) provide a real cost benefit to patients, just as samples do, particularly if the prescribing physician is unsure how the patient will respond to the therapy, and should not be discouraged.

D. Bundled Sales - §447.502

The proposed rule defines "bundled sale" but does not offer guidance on how manufacturers should apportion discounts in bundled sales arrangements other than to state that "the discounts must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement." Additional guidance is needed on how to treat a discount where the criteria for earning it is based on utilization levels covering multiple products, since the current CMS guidance on how to apportion the discount in a reimbursement situation is not very clear. For example, if a prescription rebate is paid to a health plan on a drug for achieving a 25% share of the market in its therapeutic class and the market share is based on prescription utilization of that drug and/or a new formulation of that drug, there are no purchase prices involved. The concept of bundled sales does not seem to apply to market share arrangements. It would be very helpful if CMS made it clear the circumstances that necessitate allocation of discounts on market basket contracts and application to rebates for market share covering a family of products.

E. Returns – §§447.504(h)(13); 447.505(e)(1)

The proposed rule would exclude return credits from AMP but include them in best price. We support the exclusion of return credits from AMP because such credits are not discounts or price concessions but reversals of prior sales. Historically, returns have been excluded from Non-FAMP because they were known to cause aberrations creating artificially high or low average prices due to lack of correlation between the original price and return price. More recently, CMS has excluded returns from ASP based on the same concerns. Inclusion of returns in monthly AMP would also make it more difficult to generate a value that reflects the price actually paid in the quarter used to reimburse pharmacies.

On the other hand, we oppose the inclusion of return credits in best price because it is inconsistent with the treatment in AMP and the statutory definition in section 1927(c)(1)(C) of the Social Security Act, which does not include returns. As noted, return credits are not discounts that reduce the price available or the price paid for purchased goods but are refunds for returned goods. In addition, the original sale and return transactions do not share any common identifier, which makes it extremely difficult to reverse the original sale. Finally, regardless of whether the credit for a returned unit is exactly the same as the original sale price for the unit, it makes no sense to treat the return credit as a price concession on the prior sale because the unit was neither available nor sold at the return credit amount. Therefore, we urge CMS to define best price as it is defined in the statute and not to include returns.

III. Best Price and Other Pricing Data

A. Best Price – 447.505

The proposed rule adopts the definition of best price in Section 1927(c)(1)(C) of the Social Security Act: “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States..” The National Drug Rebate Agreement likewise defines best price as “the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure...” The proposed rule states that best price includes “all sales and associated discounts and other price concessions to any entity.” To be consistent, the proposed rule must be interpreted to mean the associated discounts and price concessions are provided to the same entity to whom the drug was sold.

The statutory definition of best price has always been interpreted to mean the single lowest price to a particular customer unless the customer or transaction is exempt. However, language in the preamble to the proposed rule suggests that CMS views best price as the net amount realized by the manufacturer on a sale rather than the lowest price to a particular customer. It is critical that the final rule clarify that only discounts and price concessions to the same entity to which a drug is sold should be included in the computation of best price to that entity. A price available to one customer should not be deemed an adjustment to a price available to an entirely different customer. For example, a discount available to an indirect customer such as a hospital, is not available to the wholesaler that distributes to the hospital, and a prompt payment discount available to the wholesaler is not available to the indirect customer. Likewise, a rebate available to a health plan to reduce its prescription benefit payment to a pharmacy is not available to the pharmacy dispensing the prescription. In sum, prices to unrelated entities in the chain of distribution should not be aggregated in

determining the single lowest price to an entity, even if they concern the same unit of a drug.

In addition to being contrary to the clear language of the statute and rebate agreement, treating a managed care/PBM rebate as an adjustment to a pharmacy purchase is logistically impossible. PBMs do not identify the pharmacy that dispensed the prescription covered by the plan due to HIPAA constraints. Thus, a manufacturer cannot trace a prescription unit reimbursed by a plan back to a particular wholesale package sold to a wholesaler, retailer, or provider.

B. Reporting Issues

1. **Monthly Reporting.** We support the proposed rule decision to limit monthly reporting to AMP. There is no purpose to monthly best price or CPP and a requirement to report them would greatly increase manufacturers' compliance burden. With respect to product reports, must they be filed monthly? When a new product is launched, there may be no sales to report in the first month. However, the proposed rule suggests a product cannot be reimbursed without a product report. Finally, guidance is needed on monthly reporting of AMP when a product is discontinued.

2. **Negative AMP or Zero Sales.** The proposed rule does not address what manufacturers are to report when monthly AMP is zero or a negative number. In prior agency guidance, manufacturers were instructed to use last reported AMP and best price if there were no sales or if AMP was a negative value. Exclusion of returns helps prevent occurrences of negative AMP, but that is not the only variable. Please confirm this guidance is to be continued and applied to monthly AMP.

3. **CPP and Nominal Price Reporting.** The proposed rule specifies that customary prompt pay and nominal prices are to be reported quarterly as total aggregate dollars. However, it is unclear, in the case of authorized generics, whether the CPP paid on the generic version should be combined with the CPP on the sales of the brand, and whether sales of the generic version at nominal price should be included in the reported sales of the brand at nominal price. We do not believe combining the CPP dollars for the two NDCs serves any purpose, as no information can be gleaned from the figure. We also believe there would be no purpose in combining nominally priced sales.

Clarification is also needed as to how CPP is to be reported. The proposed rule indicates that manufacturers must submit their drug pricing data electronically via the CMS web site using specified formats. However, the quarterly report does not include a field for CPP.

4. **Corrections.** None of the drug data (price or product) reports have fields for corrections. Please provide guidance on how manufacturers are to indicate corrections.

C. Other Matters

1. Single Source Drug. The definition of covered outpatient drug in section 1927(k)(2) of the Social Security Act distinguishes between drugs approved under section 505 of the Federal Food Drug and Cosmetic Act and biological products licensed under section 351 of the Public Health Service Act. Section 1927(k)(7)(A)(iv) of the Social Security Act defines "single source drug" to mean "a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration..." A covered drug is approved under a new drug application if it follows the process specified in Section 505 of the Federal Food Drug and Cosmetic Act. Accordingly, biological products approved under section 351 of the Public Health Service should not be included in the definition of single source drug. The proposed rule improperly includes in the definition of "single source drug" biological products that are not single source drugs within the statutory definition.

2. Effective Date of Final Rule. Implementation of the proposed rule is going to present significant challenges for manufacturers and the final rule must provide sufficient time to comply with the requirements. Even though we are already in the process of reviewing and upgrading system capabilities and developing solutions to satisfy the new requirements, as CMS has publicly acknowledged, it would be a waste of resources to make changes to accommodate the proposed rule until the rule is final. We urge CMS to establish an effective date at least six months from publication of the final rule.

We hope the information provided in this letter is useful to you and that you will consider it in preparing your final rule.

Sincerely,



Donna Lee Yesner

On behalf of Allergan, Inc., Forest Laboratories, Inc. Otsuka America Pharmaceutical, Inc., and Reliant Pharmaceuticals, Inc.

The Specialty Pharmacy Coalition
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February 20, 2007

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

FEB 20 2007

RE: Medicaid Program; Prescription Drugs

Dear Ms. Norwalk,

The Specialty Pharmacy Coalition appreciates this opportunity to provide public comments on the Proposed Rule CMS-2238-P, "Medicaid Program; Prescription Drugs; Notice of Proposed Rulemaking (hereafter referred to as NPRM) published in the *Federal Register* on December 22, 2006.

The Specialty Pharmacy Coalition is comprised of the three largest national, specialty pharmacies that provide prescription drugs and biologicals for the recurring treatment of chronic diseases and clinically appropriate related services to Medicaid and non-Medicaid patients. Our members include Caremark, Inc., CuraScript, and Accredo Health, Inc., which currently provide specialty pharmacy services in all 50 states. Specialty pharmacies provide in-home delivery of certain high-cost complex treatments that require special storage and/or handling, as well as additional clinically appropriate patient services in order to ensure fully effective drug therapy.

Specialty pharmacies provide services to specific patients who have been referred by their physician. Our member companies offer patients a wide range of clinically appropriate services integral to optimizing clinical outcomes and reducing unnecessary medical complications and expenses. The following company-specific descriptions provide additional detail regarding the operations of specialty pharmacies, a narrow and highly specialized segment of the health care delivery system.

Accredo Health, Inc., a wholly-owned subsidiary of Medco Health Solutions, is one of the largest providers of specialty retail pharmacy services in the United States. Headquartered in Memphis, Tennessee, Accredo specializes in the sale of high cost drugs for the recurring treatment of chronic and potentially life threatening diseases such as hemophilia, pulmonary arterial hypertension (PAH), respiratory syncytial virus (RSV), multiple sclerosis, growth hormone deficiency, Gaucher disease and other chronic diseases.

Caremark Specialty Pharmacy Services is a leading provider of specialty medicines and biopharmaceuticals, primarily injectibles, to individuals with chronic or genetic conditions throughout the United States. There are 20 Caremark Specialty Pharmacies in 18 states, all dedicated to helping individuals by providing services for various diseases, including but not limited to, asthma, Gaucher's Disease, hemophilia and related bleeding disorders, immune disorders, multiple sclerosis, pulmonary disease, and rheumatoid arthritis. Caremark Specialty Pharmacy Services selects a personalized, pharmacist-led Care Team for each patient, which proactively reviews dosing and medication schedules, troubleshoots injection-related issues, discusses side effect management, and reinforces physician instructions to ensure that the individual's prescribed medication is administered appropriately.

CuraScript, Inc. is a wholly owned subsidiary of Express Scripts that provides managed care clients, employers, government agencies and others with specialty medications and effective specialty medication management. The company, which operates specialty pharmacies around the country, also operates nearly two dozen pharmacies dedicated to patients requiring infusion therapy. CuraScript's hallmark is its high-touch specialty care management programs ensuring that patients maximize their therapy and improve overall compliance, while offering the support patients need to manage their conditions.

The Coalition and its members welcome this opportunity to provide input on the NPRM. Our comments address two aspects of CMS' NPRM: first, the definition of the "retail pharmacy class of trade" and secondly, the definition of the term "dispensing fee." Our comments provide specific information regarding the impact of these two key definitions on the specialty pharmacy segment. Currently, CMS' NPRM does not take into consideration the unique characteristics of the specialty pharmacy environment. Our recommendations are designed to ensure continued patient access to certain highly complex therapies in a clinically appropriate setting.

Background

In the Deficit Reduction Act of 2005 (DRA), Congress fundamentally changed the underlying purpose of why a manufacturer reports an Average Manufacturer Price (AMP) for its drugs to the Secretary of Health and Human Services. The AMP was originally intended to serve as a confidential benchmark for calculating Medicaid drug rebates. The DRA instructs CMS to use AMP as a Medicaid pharmacy reimbursement benchmark for calculating Medicaid federal upper payment limits (FUL) for multiple source drugs. Furthermore, the DRA requires that AMP calculations for all drugs be provided to states and the general public via a publicly accessible website.

Single source drugs are not subject to the Medicaid FUL. However, the DRA does not specifically limit states from adopting AMP-based reimbursement for single source drugs. In the regulatory impact section of the NPRM, CMS acknowledges the possibility of "decreases to State payments for drugs not on the FUL list that may result if States change their payment methodologies."

The Coalition applauds Congress for including in § 6001(c)(3) of the DRA language requiring that the Secretary of Health and Human Services “promulgate a regulation that clarifies the requirements for, and manner in which, average manufacturer prices are determined.” The HHS Office of the Inspector General has concluded in several reports that AMPs as currently calculated are flawed.¹ In a report mandated by the DRA, OIG recently concluded “Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers’ methods of calculating AMPs are inconsistent.” OIG further concludes that “future errors or inconsistencies in manufacturers’ AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.”²

In the preamble section of the NPRM, CMS states “we believe the Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices to the retail pharmacy class of trade.” The Coalition concurs with this statement. In order for the AMP calculation to be an appropriate reimbursement benchmark based on actual prices at which retail pharmacies purchase drugs, the term “retail pharmacy” must be clearly defined and drug manufacturers must be given clear and consistent instructions on the types of sales that are included and excluded from the AMP calculation.

Overview of Specialty Pharmacy Coalition Comments

The Specialty Pharmacy Coalition recommends that CMS modify its definition of the “retail pharmacy class of trade” to specifically exclude from the definition sales of drugs and biologicals to specialty pharmacies. Manufacturers should also be instructed to exclude from their AMP calculations all sales to entities that do not meet the definition of “retail pharmacy.” The coalition bases these recommendations on the fact that specialty pharmacies are unique entities whose operations differ significantly from those of retail pharmacies. Specialty pharmacies provide high cost drugs as well as patient-specific, clinically appropriate services integral to the treatment of patients with complex chronic, terminal, and/or rare conditions. The types of drugs dispensed by specialty pharmacies, most of which require special storage, handling and preparation, are not stocked and dispensed by retail pharmacies. Similarly, the necessary clinical services cannot be provided by retail pharmacies. The exclusion of specialty pharmacy from the definition of the retail pharmacy class of trade for purposes of establishing the Medicaid AMP calculations is consistent with the definition of retail pharmacy in the Part D Medicare program, which encompasses not only the population served but also the services provided by the entity. CMS, in its preamble, specifically referenced the parallels of Part D to Medicaid. Ensuring consistency between Medicare Part D and the Medicaid program is a valuable public policy consideration.

¹ See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102, February 2005, p. 12-15. The GAO report summarizes a series of confidential OIG reports on AMP and the Medicaid rebate program.

² OIG, *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act*, A-06-06-00063, May 2006, p. 4.

Secondly, the Coalition recommends that CMS instruct states to provide appropriate reimbursement for the broad array of clinical services provided by specialty pharmacies. Because such services are not provided in the retail pharmacy setting, there are no examples of this reimbursement as related to the retail pharmacy class of trade. The patients served by the specialty pharmacy segment of the health care system rely upon these services to help ensure the effectiveness of their treatment regimen. Specialty pharmaceuticals, and the services provided by specialty pharmacies, ultimately help reduce costs to the Medicaid program and should be specifically addressed and appropriately reimbursed.

Determination of Average Manufacturer Price—Section 447.504

Definition of Retail Pharmacy Class of Trade and Determination of AMP

Proposed § 447.504 of the NPRM instructs drug manufacturers to calculate AMP as “the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade.” § 447.504(e) defines the “retail pharmacy class of trade” as any:

independent pharmacy, chain pharmacy, mail order pharmacy, 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.

In the preamble of the NPRM, the agency further states that the “retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services.” CMS also excludes from the AMP calculation manufacturer sales to nursing home and long term care pharmacies.

The Coalition is concerned that neither the instructions on the calculation of AMP in § 447.504 nor the definition of the “retail pharmacy class of trade” in § 447.504(e) specifically address the treatment of manufacturer sales to specialty pharmacies. The Coalition recommends that CMS clarify that specialty pharmacies are excluded from the “retail pharmacy class of trade” and that manufacturers should be instructed to exclude from their AMP calculations sales to entities that do not meet the definition of the “retail pharmacy class of trade.”

Specialty pharmacies provide in-home delivery of a limited number of primarily single-source injectible and infused drugs and biologicals that typically require special storage and/or handling and clinically appropriate services, and are not typically sold at retail pharmacies. Our products and clinically appropriate services are provided to chronically ill patients that are referred by their physician due to the unique type of drugs prescribed and the services necessary for their treatment. The patients we serve have complex chronic, terminal, and/or rare conditions and represent a very small percentage of the population. These chronically ill patients and their caregivers often require training in the administration of their medications, sophisticated coordination of a range of services and

supplies, patient specific dosing, assistance with side effects, ongoing compliance and safety monitoring by specially trained health professionals, and other clinically appropriate services. With the proper care, specialty pharmacy patients can avoid serious complications related to the disease or the specialty drug therapy, and reduce the need for emergency room visits, doctor visits, hospital admissions, and other medical expenses. As a result, these patients—with the proper medication and care—can lead healthier and happier lives.

These clinically appropriate services are not provided in the retail setting. Specialty pharmacies interface with their patients primarily via telephone and through in-home consultations with nurses and pharmacists employed or contracted by specialty pharmacies. We are not a traditional “walk-in” retail pharmacy. To further illustrate the differences in the breadth and type of clinically appropriate services performed in the retail and specialty pharmacy settings, we would like to provide the following comparison chart. The list on the following page is based on the services offered by our members and the typical services provided at retail pharmacy as listed in the definition of “dispensing fee” in § 447.502 of the NRPM.

Specialty Pharmacy Services	Retail Pharmacy Services
<ul style="list-style-type: none"> • Checking the computer for information about an individual's coverage • Performing drug utilization review and preferred drug list review activities • Patient specific dosing • Measurement or mixing a covered outpatient drug • Extensive beneficiary counseling and patient and caregiver education for safe and cost-effective use • Storage, handling, and shipping, of drugs with unique and sensitive requirements, including temperature monitoring. • Emergency telephone support 24 hours a day, seven days a week by nurses and pharmacists trained in specific chronic diseases. • Nursing and social work support services such as education, patient monitoring, psychological support, and community resourcing. • Adherence monitoring and education to ensure patients take their medications consistently, in the right amount and dosage, and for the full length of treatment. • Clinical management of disease-specific programs tailored to the unique needs of those with complex chronic 	<ul style="list-style-type: none"> • Checking the computer for information about an individual's coverage • Performing drug utilization review and preferred drug list review activities • Measurement or mixing a covered outpatient drug • Beneficiary counseling • Physically providing or delivering the completed prescription to the individual

<p>illnesses.</p> <ul style="list-style-type: none"> • Coordination of home nursing services that ensure that patients receive support for ongoing home infusion and self-injection in a cost-effective manner. • Monitor and supervise the utilization of specialty drugs to minimize wastage, ensure the medical necessity of ongoing treatment, and enhance clinical outcomes. • Managing the side effects of chronically ill patients, many of whom are prescribed injectible biologic products and oral cancer drugs with significant side effects. 	
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This chart clearly demonstrates that specialty pharmacies provide a breadth of clinical services not available in the retail setting. Furthermore, these services are provided only to patients referred by their physicians to specialty pharmacies for treatment.

The Coalition is also concerned that the proposed definition of the “retail pharmacy class of trade conflicts” with the definition of “retail pharmacy” under Medicare Part D. Under 42 C.F.R. § 423.100 of the Medicare Part D prescription drug program regulations, CMS defines “retail pharmacy” as “any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.” 42 C.F.R. § 423.120 further clarifies that long-term care pharmacies are not “retail” pharmacies and requires a Part D plan to separately contract with such pharmacies and assure convenient access. The same section also states that “home infusion pharmacies” are not “retail” pharmacies, and are excluded from the definition of “retail” pharmacies due to the “ongoing clinical monitoring, care coordination and home infusion nursing that is provided by staff of or affiliated with the home infusion therapy provider.” The operations of specialty pharmacies are very similar to home infusion pharmacies; in fact, our members provide home infusion therapies in addition to other treatment regimens.

A definition of “retail pharmacy” that excludes specialty pharmacy and other entities identified above as outside the retail class of trade is consistent with the Part D definition, and will result in an AMP calculation that more accurately reflects the prices at which retail pharmacies acquire prescription drugs than that proposed in the NPRM. The definition of “retail pharmacy” in the NPRM defines retail pharmacy solely based on whether the pharmacy “sells or provides the drugs to the general public.” The Part D definition encompasses both the population served and the services provided. The Coalition is also concerned that inconsistent policies in Medicaid and Medicare Part D will lead to confusion and burdensome administrative and recordkeeping requirements for drug manufacturers, health plans, wholesalers, and pharmacies.

Definitions—§ 447.502

Dispensing Fee

§ 447.502 of the NPRM defines the term “dispensing fee” as a fee which: 1) “is incurred at the point of sale and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;” 2) “includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient;” and 3) “does not include administrative costs incurred by the state in the operation of the covered outpatient drug benefit including system costs for interfacing with pharmacies.”

§ 447.502 of the NPRM also includes a list of covered retail pharmacy services which CMS proposes to include in the definition of “dispensing fee.” This list includes:

a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

This proposed list is an appropriate description of the services performed by retail pharmacies. However, as we have demonstrated above, specialty pharmacies do not meet the proposed definition of the “retail pharmacy class of trade” in § 447.504(e) of the NPRM. Thus, the list of covered activities included in the proposed definition of “dispensing fee” in § 447.502 does not reflect the clinically appropriate services provided by specialty pharmacies that are not available in retail pharmacies.

As states begin to more closely align pharmacy reimbursement with acquisition costs for multiple source and potentially single source drugs, CMS should instruct states to establish appropriate reimbursement for specialty pharmacies that reflects the costs of the unique clinically appropriate services our members provide to chronically ill patients with complex chronic, terminal, and/or rare conditions. The broad array of clinically appropriate services provided by specialty pharmacies for these clinically complex conditions are separate and distinct from those covered under the definition of “dispensing fee” defined by CMS for the retail class of trade. These clinical services reduce overall costs to the Medicaid program and should be specifically addressed and appropriately reimbursed.

We recommend that CMS consider the following two options for the appropriate reimbursement of clinically appropriate services provided by specialty pharmacies. First, CMS should provide guidance to states on the development of a specific “add-on” fee that takes into consideration the clinical services provided by specialty pharmacies to ensure the safety and effectiveness of patient treatment. CMS has recognized the need for this type of payment structure most recently through the development of a Medicare Part B per unit administration fee for blood clotting factor as mandated in the MMA. The Coalition recognizes that an “add-on” fee for clinically appropriate specialty pharmacy services is not directly addressed in the DRA; however, in order to ensure the continued

provision of these necessary services, such “add-on” fees are fundamental. Secondly, CMS could provide guidance to states regarding the importance of dispensing fees specific to specialty pharmacies to compensate for the clinically necessary services required for therapy safety and efficacy. The Coalition believes that these additional dispensing fees could address many of the concerns raised in special handling, clinical monitoring, and management of these fragile patients.

We look forward to engaging CMS and the states in this effort to ensure that chronically ill Medicaid beneficiaries continue to have access to the clinically appropriate services provided by specialty pharmacies.

Conclusion

In conclusion, we share the agency’s commitment to implementing Congress’s intent that AMP calculations reflect actual sales to retail pharmacies. In order to reflect congressional intent, we recommend that CMS modify its definition of the “retail pharmacy class of trade” to specifically exclude from the definition sales of drugs and biologicals to specialty pharmacy. Secondly, we urge CMS to instruct manufacturers to exclude from the AMP calculation sales to entities that do not meet the definition of “retail pharmacy.” Lastly, the Coalition recommends that CMS instruct states to provide appropriate reimbursement for the broad array of clinically appropriate services provided by specialty pharmacies.

On behalf of the Specialty Pharmacy Coalition and its members, we thank the agency for this opportunity to provide our comments on Proposed Rule CMS-2238-P. We welcome any questions you may have about the unique characteristics of the specialty pharmacy class of trade. Furthermore, the Coalition and its members look forward to working with the agency in the future to ensure the best possible care for chronically ill Medicaid beneficiaries.

Sincerely,



Michael Hess
Chief Legal Counsel
Accredo Health, Inc.



Dave Golding
Executive Vice President, Specialty Pharmacy Services
Caremark Inc.

Handwritten signature of Keith Ebling.

Keith Ebling
Senior Vice President and General Counsel
CuraScript, Inc.



**Boehringer
Ingelheim**

rec'd
FEB 20 2007 *Ep*

**Boehringer Ingelheim
Pharmaceuticals Inc.**

VIA HAND DELIVERY
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Department of Health and Human Services
Room 445-G
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February 20, 2007

**CMS-2238-P;
Comments to the Medicaid Program
Prescription Drugs Proposed Rule**

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Dear Sir or Madam

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On behalf of Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Ingelheim" or "the Company"), we are pleased to submit these comments on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Regulation ("Proposed Regulation") implementing provisions of the Deficit Reduction Act of 2005 ("DRA"). The Proposed Regulation would modify how "Average Manufacturer Price" ("AMP") is calculated and implement other changes related to Medicaid Rebate policies.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies, with a broad spectrum of therapeutic products including both branded and multisource products. As a result, it will be directly affected by the changes in AMP and other policies being proposed by CMS.

Boehringer Ingelheim has had an opportunity to review other comments being submitted by the various industry trade associations representing manufacturers of branded and multisource products, and in general, we support the points being made there about the need for greater clarity in the Proposed Regulation. However, the Company has two significant points that it wishes to emphasize and therefore, we are taking this opportunity to discuss those points here.



A. Uniformity between 340B and the Medicaid Programs.

As with other pharmaceutical companies, Boehringer Ingelheim participates in various federal programs that affect reimbursement of its products. Under the Medicaid Program, Boehringer Ingelheim pays rebates to the states that are calculated, in large part, based on the drug's Average Manufacturer Price or AMP. Similarly, the Company also participates in the federal government's 340B Program, which requires manufacturers to charge at or below certain defined prices (usually referred to as the 340B ceiling price) to qualified entities, including community health centers, public hospitals, and various Federal grantees. Like the Medicaid Program, the 340B ceiling price also is based, in major part, on AMP. However, while the DRA changed the definition of AMP for the Medicaid Program in order to exclude from AMP prompt payment discounts, the AMP used in the 340B *includes* the prompt pay discounts. This inconsistency requires manufacturers to maintain two separate sets of calculations, increases the costs and burdens of compliance, and will significantly increase the risk of error.

In order to understand how this situation arose, it is helpful to review the history of the AMP calculation. Prior to the passage of the DRA, in 2005, AMP was defined in statute as being based on prices paid to manufacturers by wholesalers for drugs distributed to the retail class of trade, "after deducting customary prompt pay discounts." However, when Congress revised the definition in the DRA, it required that AMP be calculated, without regard to prompt pay discounts (i.e., prompt pay discounts are no longer deducted from AMP.) In its January 30, 2007 letter to pharmaceutical manufacturers, the Office of Pharmacy Affairs ("OPA"), which is part of HHS' Health Resources and Services Administration ("HRSA"), clarified the definition of AMP to be used in 340B ceiling price calculations. The OPA states:

Although the Deficit Reduction Act amended the statutory definition of Average Manufacturers Price for purposes of Medicaid by removing the deduction for customary prompt payment discounts, Section 340B(c) of the Public Health Service Act states, "Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section." Accordingly, manufacturers that have signed pharmaceutical pricing agreements (PPAs) must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts.¹

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

Clearly, calculating the same reference price in two different ways seems illogical, burdensome, and likely to result in errors. As noted above, both 340B ceiling prices and Medicaid rebates are based on the same reference price—"average manufacturer price." In fact, the 340B ceiling price is basically the AMP minus the amount of the rebate paid on a single unit of the

¹ Jimmy Mitchell, Director of OPA, "Dear Pharmaceutical Manufacturer Letter Clarifying the Definition of Average Manufacturer Price" (January 30, 2007), available at <http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm>.



product. The OPA policy will require that manufacturers maintain two separate sets of calculations for their AMP, one including prompt pay discounts, and one excluding them. To have to maintain separate calculations for all such products will increase the time and expense of participating in the 340B and Medicaid programs, and will almost certainly result in errors, as manufacturers try to keep track of two separate sets of prices for each of their numerous products. Moreover, the OPA has given no guidance on how to handle other issues that will now be defined by the Proposed Regulation. For example, the Proposed Regulation clarifies how numerous other issues are to be treated for AMP under Medicaid, such as SPAPs, administrative and bona fide service fees, authorized generics and bundled sales, just to name a few. OPA has given no guidance, however, concerning whether or not these areas should be treated the same under the 340B program, or whether, as with prompt pay discounts, they are subject to different treatment. Obviously, the calculation will become even more difficult, if there are numerous differences in how these various items are treated.

Boehringer Ingelheim recognizes that OPA is not directly responsible for the issuance of the Proposed Regulation, and thus, the issues raised here may not seem germane to these comments. Nonetheless, these comments represent the best opportunity to raise this troubling issue and, we hope, to obtain an expeditious resolution. Moreover, OPA has stated that it welcomes comments on how best to implement the 340B program in light of the recent DRA changes; thus, it is important to raise the question here, in the hope that CMS and OPA can define terms consistently, to the extent possible. We believe there are other ways to resolve this issue that would reduce the burden on all parties, while still giving OPA access to the information that it needs for the 340B program. Therefore, we are requesting the opportunity to meet with CMS and OPA to discuss possible solutions that could be implemented to achieve those goals.

Further, as CMS and OPA (and its parent HRSA) are components of the Department of Health and Human Services, we believe it is vital that all of the affected entities work with the Secretary's office to resolve what is clearly an illogical situation. If necessary, the agency should seek assistance from Congress to make the definitions of these two terms consistent. In that way, at least manufacturers would be spared having to recalculate the same basic information in two different ways.

B. CMS should permit "smoothing" over a 12-month period

In the Preamble to the Proposed Rule, CMS also requests comments on how to adjust for rebates or other price concessions that will not be ascertainable until after the end of the month. As CMS itself notes, "if the monthly AMP were calculated simply using sales in that month, these pricing practices might result in fluctuations between AMP for the first two months and the AMP for the third month in the calendar quarter."² CMS therefore states that it will permit end of quarter rebates and other price concessions to be allocated to the monthly AMPs reported. However, it also

² 71 Fed. Reg. at 77186



However, it also asks for comments on whether it should allow a 12 month rolling average estimate of all lagged discounts for both monthly and quarterly AMPs.

Boehringer Ingelheim appreciates CMS' request for comments on this area. We recognize that CMS is attempting to keep the information reported as accurate as possible, while minimizing fluctuations that will affect its reliability. However, because of the nature of many types of price concessions commonly used in the pharmaceutical industry, such as chargebacks and rebates, there must be a mechanism in place to adjust the AMP to reflect changes in a prior month's sales. Moreover, all of these adjustments will not occur within a single quarter. Thus, a rebate or chargeback may often apply to a sale that took place not in the current quarter, but rather to one that occurred in the previous quarter or one even further removed. Thus, Boehringer Ingelheim does not believe it is sufficient simply to revise monthly AMPs based on the expected lagged discounts during that quarter. It is preferable to calculate a percentage that reflects a 12 month rolling average, just as is done in the case of the ASP.³ That allows for a more accurate reporting of lagged price concessions, and ensures that discounts paid in one quarter are properly captured, even if they relate to sales that occurred one or even two quarters earlier. As a result, we urge CMS to utilize a 12 month rolling average, comparable to that used for ASP.

We appreciate the opportunity to comment on these significant and far reaching proposals. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely yours,

A handwritten signature in cursive script that reads "Christine G. Marsh".

Christine G. Marsh
Executive Director, Contracts and Pricing

³ See 42 C.F.R. §414.804.



February 20, 2007

Via Courier

Leslie Norwalk, Esq.
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Rec'd FEB 20 2007 *ع*

**RE: Proposed Rule To Implement Provisions of DRA Pertaining to
Prescription Drugs under the Medicaid Program;
(Docket No. CMS--2238--P)**

Dear Administrator Norwalk:

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). FMI is highly concerned about the impact of the proposed rule on its supermarket pharmacy members. As CMS notes in the proposed rule, the use of Average Manufacturer Price (AMP) as a benchmark for pharmacy reimbursement represents a departure from the previous role of AMP in the Medicaid rebate calculation. Understanding the difficulties that the agency faces in reconciling these conflicting roles for AMP, we believe that several of the decisions CMS has proposed would unduly reduce AMP. Our comments and recommendations are discussed more fully below and in the attached Appendix A, which translates our comments into regulatory language for your consideration.

FMI conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies - food retailers and wholesalers - in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of \$340 billion - three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

FMI's retail members also operate more than 10,000 in-store pharmacy departments. We estimate that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward

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larger store formats and the convenience of one-stop shopping, we anticipate that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

A. Executive Summary

FMI urges CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Recent studies suggest that Federal Upper Limits (FULs) based on AMP may result in ingredient cost reimbursement that is below pharmacy acquisition cost.¹ While FMI is not certain that this situation can be fully addressed in regulations, we believe that CMS should take the following steps to mitigate this problem:

- Restrict the scope of discounts included in the “retail class of trade” to reflect only those prices that are provided to wholesalers for drugs distributed to retail pharmacies;
- Define “wholesaler” in a manner that better reflects current law and practice;
- Remove from the proposed rule’s definition of AMP sales to PBMs, outpatient hospitals, clinics and mail-order pharmacies that fall clearly outside of the statutory definition of AMP;
- Remove from AMP those prices that Congress excluded from “best price” to allow for deep discounts that could otherwise artificially deflate AMP;
- Set FULs based on the average AMP of various therapeutic alternatives, rather than the lowest cost alternative;
- Exercise discretion to delay publication of AMP information to ensure that the consequences of publishing this information are fully understood;
- Reduce the potential for volatility in the AMP-based reimbursement system by removing a larger number of outliers when establishing FULs;
- Base FULs on the AMPs of those products that are nationally available and in sufficient supply to meet the needs of pharmacies over time;
- Revise the regulatory definition of “dispensing fee” to ensure that all pharmacy costs are identified; and
- Require states to update their Medicaid dispensing fees to be sure that these fees are adequate in light of newly implemented DRA policies, particularly to ensure appropriate utilization of generic drugs.

The remainder of this letter provides more details on each of these issues as well as proposed regulatory language in Appendix A.

¹ Government Accountability Office “Medicaid Outpatient Prescription Drugs: Estimated 2007 Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs”, Letter to Rep. Joe Barton (R-TX) (December 22, 2006).

B. Policy Context

Supermarket pharmacy profit margins are generally only a very small percent of total revenue, far lower than most other businesses. In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. FMI and its members are particularly concerned about the impact of the DRA's FUL policies on retail pharmacies. According to the GAO's comparison of AMP-based FULs to pharmacy acquisition costs, AMP-based FULs were 36% lower than average pharmacy acquisition costs when calculated using information from the first quarter of 2006. To the extent that FULs are below pharmacy acquisition costs for generic drugs, our members may find it increasingly difficult to serve Medicaid patients. This situation is exacerbated by dispensing fee amounts at the state level that are far below the costs our members incur to dispense prescription drugs to Medicaid patients.

FMI is aware that the use of AMP in setting FULs is dictated by the DRA, and of the difficulty facing the agency in balancing between the use of AMP for reimbursement and its use in the calculation of manufacturer rebates to the Medicaid program. Along with others in the pharmacy community, FMI is involved in efforts to address this problem legislatively. However, as we discuss in the balance of this letter, we believe that CMS has significant discretion to mitigate the severity of the problem, discretion that the agency has not fully exercised. We urge CMS to emphasize the role of AMP as a reimbursement benchmark in the final rule to ensure that our member pharmacies can continue to serve Medicaid patients.

C. Analysis of Issues

1. Revise Proposed AMP Definition To Exclude Sales to Mail Order and PBMs That Are Outside the Statutory Definition of AMP.

While FMI recognizes the difficulties that the DRA has imposed on CMS by requiring AMP to be used for a very distinct new purpose, we believe that CMS errs in the proposed rule by defining AMP as encompassing a variety of sales that are outside of the statutory definition of AMP. The statute is clear: AMP is the *average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.*² In contrast, CMS proposes to include price structures that are beyond the statutory definition either because they do not reflect prices paid by true wholesalers or because they do not reflect discounts and concessions that are ultimately realized by the retail class of trade. Accordingly, and as explained more fully below, CMS has proposed a regulatory definition for AMP that is neither adequately supported by the statute nor an effective benchmark for pharmacy reimbursement.³

² §1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-8(k)(1)).

³ As noted, FMI does not believe that AMP – even as defined by the statute – can be an effective benchmark for pharmacy reimbursement under the Medicaid program. Nonetheless, given the enactment of the

a. Exclude Discounts Given to PBMs and Mail Order Pharmacies Because These Businesses are Outside the Retail Class of Trade.

FMI's primary concerns with the proposed definition of AMP are the overly broad view of retail class of trade and the definition of wholesaler. Section 1927(k)(1) of the Social Security Act defines AMP in relevant part 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*." We believe that this definition in fact counsels that AMP "should only reflect prices of sales to those pharmacies which dispense drugs to the general public", an option that CMS chose to reject as inconsistent with "past policy."⁴ We would note, however, that the "past policy" to which CMS refers was implemented at a time when AMP was not being used for pharmacy reimbursement purposes, but only for the purpose of calculating rebates owed by manufacturers to CMS and the states. Accordingly, CMS is not bound by its past policy, nor should the agency feel constrained to operate within it. Rather, given the new task imposed on CMS by the DRA, CMS should establish a new policy reflective of the multiple purposes that AMP must now serve.

Indeed, reading the statutory definition of AMP in light of its new use as a reimbursement benchmark counsels for excluding sales to PBMs, mail-order pharmacies and other entities that are outside the retail class of trade. The inclusion of PBM discounts and mail order prices that are clearly not accessible to retail pharmacies artificially deflates AMP, potentially impeding the convenient access of Medicaid beneficiaries to supermarket pharmacies if these retail outlets cannot receive adequate reimbursement for their pharmaceutical acquisition costs for generic drugs.

In addition, it is our understanding that some manufacturers consider both mail order pharmacies and PBMs to be separate and distinct from the retail class of trade. Indeed, it is difficult to describe PBMs as falling within the retail class of trade, as their pharmacy benefit management functions are not directly involved in the supply chain for pharmaceuticals. Only in their role as mail order pharmacies do PBMs typically participate directly in the purchase and delivery of prescription drugs, an activity which is also outside the retail class of trade. Mail order pharmacies take title and deliver products to patients but are a separate and distinct option for consumers in contrast to the supermarket and community pharmacies that are typically considered "retail". Indeed, in its rule implementing the Medicare Modernization Act, CMS explicitly excludes mail order pharmacies from its definition of "retail pharmacy."⁵

DRA, we recognize that Congress has made a determination in this regard, and CMS is obligated to implement that legislative decision.

⁴ 71 Fed. Reg. at 77178.

⁵ 70 Fed. Reg. 4493, 4535 (January 28, 2005).

b. Discounts Given to PBMs and Mail Order Pharmacies – Entities Typically Outside of the Wholesaler Distribution System – Cannot Be Included in AMP

Not only does the statute limit the data to be used to calculate AMP to prices paid for drugs distributed within the retail class of trade, the statute expressly defines AMP as the price *paid by wholesalers*. Therefore, although discounts to PBMs and mail order pharmacies may affect the “net price realized by manufacturers,” as asserted by CMS, the statute requires the use of wholesaler pricing in the determination of AMP. Indeed, many of the sales to PBMs and mail order do not flow through wholesalers at all, so the discounts received by PBMs and mail order generally do not affect the price paid by “wholesalers,” as this term is typically defined.

Specifically, CMS proposes to define “wholesaler,” as follows:

Any entity (including a pharmacy, chain of pharmacies or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drugs.

Proposed 42 CFR 477.504(f). The proposed regulatory definition, which includes retail outlets, overreaches common and statutory wholesaler definitions resulting in a situation that is contrary to state licensing practices and conflicts with related federal statutes.

First, treating pharmacies as wholesalers is inappropriate and could unduly burden FMI’s members with new licensing requirements at the state level. Supermarket pharmacies are licensed as pharmacies – not wholesalers, to which different licensing and regulatory requirements apply. Accordingly, supermarket pharmacies are not properly considered wholesalers.

Moreover, the distribution functions typically performed by wholesalers are far different from the administrative functions performed by PBMs. Section 510(g) of the Federal Food, Drug, and Cosmetic Act defines “wholesale distributor” as an entity “who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.”⁶ As discussed, PBMs generally do not take title to prescription drugs except in limited instances, and then generally because they are operating as mail order pharmacies and not in their traditional functions as PBMs. Therefore, CMS should not include PBMs within the regulatory “wholesaler” definition either.

⁶ 21 U.S.C. 360.

c. AMP Should Not Include Discounts that Fall Outside the Medicaid Program

Many of the discounts that CMS seeks to include within the definition of AMP are given by manufacturers to entities that are able to increase the market share of particular products through therapeutic switching and other mechanisms. Under the Medicaid program, which prohibits formularies and a variety of other cost containment tools, pharmacies cannot engage in these practices and are, therefore, ineligible for many of the discounts predicated on these practices. Consequently, it is inappropriate to apply these discounts to AMP when it will be used as a Medicaid pharmaceutical reimbursement benchmark.

For these reasons, FMI believes that CMS has erred in its proposed definition of AMP. We urge CMS to promulgate a final regulatory definition of AMP consistent with the recommendations in Appendix A of our comments that omits pricing given to PBMs and mail order pharmacies from the definition and, therefore, will better reflect the retail class of trade and wholesaler elements of the statutory definition.

2. Revise Proposed AMP Definition To Exclude Sales Excluded from Medicaid's "Best Price"

CMS proposes to include within the definition of AMP certain sales, notably sales to Part D plans and State Pharmacy Assistance Program (S-PAPs), that are excluded from Medicaid's "best price". These sales are excluded from "best price" to provide deeper discounts to S-PAPs and Part D plans. Indeed, the Congressional Budget Office specifically scored the exemption from "best price" for sales to Part D plans as producing savings because it "gives those plans more leeway to negotiate steeper price discounts from manufacturers since those manufacturers will not have to pass on the same discount to Medicaid."⁷

The "best price" exclusion reflects the policy judgment of Congress that deeper discounts should be available for particular classes of sales than are typically available to the retail marketplace. The exclusion has been available for many years for various government sales and was extended to prescription drug plans under Medicare Part D in the Medicare Modernization Act.

In contrast to S-PAPs and Part D plans, sales to retail pharmacists are not exempt from best price, and pharmacists are unlikely to receive the level of discounts available to those entities. Thus, including sales that are exempt from "best price" in AMP will artificially lower AMP as a reimbursement benchmark by including discounts in AMP to which

⁷ "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit." (July 2004). <http://www.cbo.gov/ftpdocs/56xx/doc5668/07-21-Medicare.pdf>

pharmacists do not have access. FMI therefore urges CMS to exclude from the definition of AMP those sales that are exempt from “best price” under §1927(c)(1)(C)(i) of the Social Security Act.

3. Statute Requires CMS To Use Weighted Average of AMPs to Set FULs, Not Lowest Cost Therapeutic Alternative

CMS proposes to set AMP-based FULs at 250% of the AMP of the lowest cost therapeutic alternative. While the DRA requires FULs to be set at 250% of AMP, the statute itself does not reference the lowest therapeutic alternative – that benchmark was defined in previous CMS regulations.

Thus, CMS retains the discretion to improve pharmacy reimbursement by using a weighted average of all therapeutic alternatives of a particular prescription drug and should, in fact, do so to reflect the standard set by the statute properly. Particularly in light of the GAO’s findings that AMP-based FULs are below pharmacy acquisition costs, FMI believes that the use of a weighted average could mitigate the number of instances where pharmacies are to be reimbursed below their acquisition costs and urges CMS to change to a weighted average FUL calculation in the final rule.

4. CMS Should Exercise Its Discretion To Delay Publication of AMP Data

FMI believes that the publication of AMP data has the potential to distort the marketplace for generic drugs, with potentially serious anti-competitive effects. Publishing AMP data could create a floor on the price discounts that generic manufacturers are willing to offer, reducing the level of competition between generic manufacturers with potentially significant negative effects on the Medicaid program.

If AMP data are published, manufacturers may find it difficult to offer discounts to some customers and not to others, as most customers will be unwilling to pay more than the average price. In this scenario, manufacturers will be more likely to sell to all buyers at the same rates, eliminating the benefits of competition that could otherwise accrue to the marketplace. In the case of Medicaid, the government will bear most of the consequences of this reduced competition -- the prices paid to manufacturers on average will increase, driving AMP-based reimbursement up also.

FMI and others are exploring legislation to ensure that AMP data remain confidential. In the interim, we believe that CMS has the discretion to delay publication of this information and we urge the agency to exercise this discretion.

5. CMS Should Reduce Volatility by Excluding Outlier Prices Less than 10 Percent of Next Highest AMP, Implementing Smoothing Mechanisms Similar to ASP

FMI is concerned about the potential for volatility in the drug reimbursement system, particularly in light of the CMS decision to rely on monthly AMP reports in setting FUL rates. We believe that relying on monthly AMP reports to set FULs and seeking to update FULs on a monthly basis could create significant volatility in the system, along with an undue burden on states seeking to administer FUL rates. We understand that Average Sales Price (ASP) based rates for certain products reimbursed under Medicare Part B have been highly volatile – even though ASP rates are calculated quarterly – and we believe that smoothing mechanisms will also be needed for AMP-based rates.

a. Possible Range Between AMP of Lowest Therapeutic Alternative and Next Highest AMP Should be Reduced

To avoid setting FULs based on “very low” AMPs, CMS proposes to set each FUL based on the lowest AMP “that is not less than 30 percent of the next highest AMP for that drug.”⁸ However, as the competition between generic therapeutic alternatives tends to reduce differences between competing products to very small levels, the proposed 70 percent range would still capture and incorporate a wide range of outliers in AMP-based FULs.

Thus, to reduce volatility and ensure a nationally available AMP, we encourage CMS to exclude “outlier” percentages that are more than 10 percent below the next highest AMP. A wider gap between therapeutic alternatives would likely be indicative of problems in AMP data or temporary spikes that would not actually reflect prices nationally available in the marketplace. Using a small percentage range will also improve the ability of pharmacists to purchase prescription drugs at prices below the FUL and better serve the agency’s stated purpose of ensuring that drugs are “nationally available at the FUL price.”⁹

b. AMP Should Employ “Smoothing” Mechanisms Similar to Those Used in the ASP Reporting System Under Medicare Part B.

In Medicare Part B, CMS created various mechanisms for “smoothing” ASP reporting to limit volatility. For example, manufacturers must calculate “lagged discounts” using a percentage methodology that reduces the potential for these discounts to be over-stated or understated in a particular quarter. The proposed rule for AMP does not employ such a smoothing methodology, which could contribute to volatility in Medicaid reimbursement for generic drugs. FMI urges CMS to require manufacturers to “smooth” those discounts that are included in AMP.

⁸ 71 Fed. Reg. at 77188.

⁹ *Id.*

c. CMS Must Ensure That FULs Are Based on Nationally Available Prices.

Finally, CMS should ensure that no FUL is based on an AMP for a generic pharmaceutical produced by a manufacturer that does not make the product nationally available. It is common for generic manufacturers to work directly with select pharmacy chains and wholesalers to meet market share goals in a manner that may not provide national access to their products. Consistent with others in the industry, FMI believes that AMP should only be calculated based on generic products that are AB-rated in the FDA *Orange Book* and are consistently available from the three major national wholesalers in supplies adequate to afford national distribution. Products that are erratically available or that are available only in limited supplies should be excluded from the weighted average AMP calculation. We are particularly concerned that a FUL could be set by a manufacturer undercutting the market, but without enough supply to meet market demands for an extended period of time. Particularly if CMS does not move to a FUL based on weighted average AMP, we would urge the agency to take steps to ensure that each AMP used to represent a FUL reflects a product that continues to be available to all retail pharmacies.

6. CMS Should Take All Necessary Measures To Ensure Adequacy of State Dispensing Fees

In order to protect convenient access to prescription drugs for Medicaid beneficiaries, CMS must ensure that the final regulatory definition of “dispensing fee” captures all of the applicable pharmacy operating costs. Specifically, the definition of dispensing fee in the proposed rule should be amended to include medication therapy management services and a reasonable return for pharmacies. As Medicaid may no longer adequately reimburse pharmacies for the ingredient costs of generic drugs, setting dispensing fees adequate to cover pharmacy costs in delivering pharmaceuticals to Medicaid beneficiaries is absolutely essential. (Suggested regulatory language for CMS’s consideration in this regard is included in Appendix A.)

According to various sources, the current average dispensing fee at the state level is approximately \$4.50. Recent studies of the actual costs to pharmacists to dispense prescription drugs have placed those dispensing costs at between \$9 and \$14 per prescription, depending on the state, with a national average of more than \$10.¹⁰ Thus, dispensing fees at the state level are clearly inadequate to cover pharmacy costs.

Accordingly, CMS should take an active role in informing the states about the need to adjust dispensing fees, especially in light of the DRA FUL policy. CMS should require each state to make a specific finding that the existing dispensing fee structure is not only adequate

¹⁰ “National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies”, Grant Thornton LLP (January 2007). Also, C. Mullins and A. Davidoff, et al, “Analysis of Cost of Prescription Drug Dispensing in Maryland” (December 2006).

to cover pharmacy costs (including a reasonable return), but also that these fees provide adequate incentives for generic usage in light of the revised FUL policy. CMS should direct states to increase dispensing fees that will not allow for adequate generic usage.

These suggestions reflect Congressional intent in enacting the DRA. Specifically, during the DRA debate, Senator Grassley stated that “states will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions” in response to the revised FUL policy.¹¹ Without significant changes in state dispensing fees, pharmacy incentives to encourage generic utilization will be significantly reduced, with the corresponding potential to reduce greatly the savings that the DRA’s imposition of AMP-based FULs was intended to provide. Given that brand name prescriptions cost an average \$12 while generic drugs average \$20 per prescription, the impact of reduced generic utilization could be significant indeed. State dispensing fees should be set in a manner that provides adequate incentives for the use of generic drugs and protects the convenient access of Medicaid beneficiaries to retail supermarket pharmacies.

D. Conclusion

FMI appreciates the opportunity to offer these comments on the impact that CMS’s proposed regulation will have on supermarket pharmacies. We respectfully request that you consider our comments fully on the record and that you utilize the regulatory changes proposed in Appendix A of our comments.

We look forward to working with CMS on these issues in the future. Please feel free to call me or Deborah White, FMI’s Associate General Counsel and Vice President of Regulatory Affairs at 202-220-0614, with any questions you might have.

Sincerely,



Tim Hammonds
President and CEO

¹¹ See Congressional Record, Senate, November 3, 2005, p. S12326 (Colloquy between Senators Grassley and Reed).

APPENDIX A:
Specific Regulatory Proposals

§447.502 Definitions

Amend paragraph 2 of the definition of “dispensing fee” as follows:

Dispensing fee means the fee which – ...

“(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist’s time in checking the computer for information about an individual’s coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling (including medication therapy management services), physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy (including a reasonable profit); and”.

S447.504 Determination of AMP

(e) *Retail pharmacy class of trade* means 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.

(f) *Wholesaler* means any entity (~~including a pharmacy, chain of pharmacies or PBM~~) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug that is licensed in a state as a wholesale distributor of pharmaceuticals.

Amend subsection (g) by striking paragraphs 3, 6, 7, 8, 9 and 12 and re-designating paragraph numbers accordingly.

Amend subsection (h) by inserting a new paragraph after paragraph 3 (and re-designating paragraph numbers accordingly) that reads as follows: “Sales exempt from best price (as defined by §447.505).”

Amend subsection (i)(1) by striking “PBM price concessions,”.

§447.514 Upper Limits for multiple source drugs

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the weighted average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) ~~for the least costly therapeutic equivalent~~ all therapeutic equivalents for sale nationally (as described in subsection (c)).

Amend subsection (c) by:

- (1) striking "30" in paragraph 2 and replacing it with "90"; and
- (2) inserting a new paragraph as follows:

“(4) Any product that is not consistently available from the three largest wholesalers in amounts reasonably adequate to supply the retail pharmacy sector will be excluded from the FUL group.”

§447.518 State plan requirements, findings and assurances

Amend subsection (b)(1) by:

- (1) in clause (i) by striking at the end “and”;
- (2) in clause (ii) striking the period at the end and inserting in lieu thereof “; and”;
and
- (3) inserting the following new clause:

“(iii) In the aggregate, the dispensing fees paid to pharmacies cover the costs described in §447.502 and are designed to encourage the utilization of multiple source drugs where appropriate.”