KEYSTONE
PHARMACY PURCHASING ALLIANCE, INC.

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

1/15/2007

Dear Ms. Leslie V Norwalk, ESQ:

I thank you for the opportunity to comment on the proposed rule changes that will implement the provisions of the Deficit Reduction Act of 2005 (DRA).

My first comments, after reading the 150 pages are that there seems to be some problems with the assumptions that influenced the final rulings. Also, many of these rules use a flawed GAO report, "*Medicaid Drug Rebate Program – "Inadequate Oversight Raises Concerns about Rebates Paid to States"* (GAO-05-102), dated February 2005 as its basis for many parts of this ruling.

In press releases, after the implementation of Medicare Part D, you personally praised the efforts of Community Pharmacy (Chain Store & Independent) for the help they provided during these troubled times. Billions of dollars have already been saved by the Federal Government, and most importantly, the "senior" consumer has much better access to its pharmaceutical needs. Now you are asking Community Pharmacy to give up another $8.4 Billion dollars over the next 5 years. This is not the "Thank You" we expected.

This ruling only pertains to multiple source drugs (generics), which is within itself a very complicated and time sensitive part of Pharmacy. Prices change on a daily basis, some increased & others decreased due to market place availability and the number of manufacturers supplying the product. Updating pricing monthly, with a 30 day window for the manufactures to supply pricing means that pricing will always be 60 days behind the market place pricing; while invoicing to Community Pharmacy changes daily.

While everyone agrees that Average Wholesale Price (AWP) is no longer an accurate basis for pricing, all I can say at this point about Average Manufacturer's Price (AMP) is that AMP could also be an acronym for **"Ain't My Price"**. The one major flaw I see in your calculation for determining Federal Upper Limit (FUL) using AMP is that distribution costs added to this price by Wholesalers & Distributors is not calculated in your formula. While your people may feel that this is a minimal mark-up (like with Brand Name Products), in reality this figure ranges at a low of 15% to a high of about 35%. With Independents, 95% of their purchases of generics are through Wholesalers & Distributors. Chain store purchases of generics through Wholesalers & Distributors are lower, but their net price after warehousing and distribution of products purchased direct from the manufacturers are very similar to the Independents invoice pricing.

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KEYSTONE
PHARMACY PURCHASING ALLIANCE, INC.

Wholesalers in the United States are very important in the day-to-day operation of a pharmacy and only because of them are drugs available to the consumer in a timely manner. Maybe the authors of these rulings should spend a day at a wholesaler's distribution center and see the technology involved in this process. Without the wholesalers, distribution of product to the end user would be in chaos.

Now let's get into your specific requests for comments:

Including mail-order pricing into the pricing formula to calculate FUL's –
The fact that manufacturers have instituted different prices for different categories is discriminatory and has been in Federal Court for the past 11 years. That being said, including mail-order pricing in the formula is wrong and in its stead there should be a Retail Average Manufacturers Price (RAMP) and a Mail-Order Average Manufacturers Price (MAMP), and reimbursement to these two entities should use the RAMP price or the MAMP price. Better yet, the Federal Government should mandate a "One Price Policy" by all manufacturers to all categories, thereby lowering the price to the consumer, leveling the playing field and ending discriminatory pricing. It seems to work in Europe and Canada – but PHRMA spends millions to prevent this from occurring in the United States

Including rebates to PBM's in the calculation of AMP –
You state in your rulings that you have no way of knowing what portion of these rebates are passed onto Community Pharmacy or the consumer. Allow me to simplify this matter for you – ***NONE OF THESE DOLLARS ARE PASSED ONTO COMMUNITY PHARMACY OR THE CONSUMER*** – The present day PBM's (no longer just an administrator) is big business and their profits are astronomical and at the point where they are unconscionably increasing the costs of health care. There are multiple reports showing this that are available to you by our national organizations and the business pages of every newspaper report "settlements" made by PBM's to the States, HMO's, etc. quite often.

Effect of these new proposed rulings on the growth of dispensing of generics in the future, and to what extent PBM's act as wholesalers.
Over the past few years generic utilization has greatly increased saving the government billions of dollars. This utilization has increased from about 30% ten years ago to approximately 55% now. Decreasing reimbursement for generics will reverse this increase in utilization very quickly and more than make up the proposed $8.4 Billion in savings. As for the PBM's acting as wholesalers, they own the Mail-Order houses, mandate the use of the mail-order by consumers using unfair business practices (co-pay differentials) and take advantage of their mail-order category to obtain discriminatory pricing which they do not pass on to consumer or the end payor. They do not actually act as a wholesaler, but use the "charge-back system" developed by the wholesalers and manufacturers to greatly increase their profits. They also spend millions of

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dollars fighting "transparency" law suits throughout the country, rather than allowing any one the ability to see "the money trail".

Allowing each State to set Professional Fees:
Many cost surveys have been published over the past few years showing that the actual costs by the Pharmacy Community to dispense a prescription are in the range of $9.50. With each State having its own budgetary problems, these surveys have been ignored and there is no reason to think that the States will mandate a fair reimbursement. This would be an excellent opportunity for CMS to mandate a $10.00 professional Fee for Brand products and a $15.00 Professional Fee for generics. This would assure that generic utilization increases and access by the consumer of their prescription needs would not be seriously affected. Also at the same time, rather than instituting a complicated method of calculating AMP by manufacturers, why not use the present Wholesale Acquisition Cost (WAC) which is a much better picture of a stores acquisition cost and is already readily available and published by the pricing guides. Of course, the above mandated Professional Fees must also be included in the formula.

Including in the AMP calculation, rebates paid to SCHIP, Medicare Part D Plans, and SPAP Plans.
You are excluding rebates to Medicaid, DoD, HIS, and DVA because prices to these entities are not available to the Retail Pharmacy Trade. What makes you think that rebates offered to SCHIP, Medicare Part D Plans, and SPAP Plans are available to the Retail Pharmacy Trade? All your assumptions in this portion of the proposed rules are definitely flawed and should be revisited.

Initiation of the Definition of Fair Market Value:
In this section, you mention Medicare Part B initiating a Fair Market Value for their limited number of drugs and whether this method should be instituted in these rulings.
First, in many cases Part B drugs can not be bought by the Pharmacy Community at the prices set. Initiating this method would transform Chain Pharmacy Stores into variety stores and Independent Pharmacy would cease to exist. Access to Prescription drugs would cease to exist and hospital emergency rooms would become understaffed clinics.
Secondly, let me just say **NO**.

Pricing for new generic Products entering the Market-Place:
Over the past few years when a brand name product nears the end of their patent, the manufacturer works out a deal with just one generic manufacturer to have exclusive rights for a period of about 6 months. In many cases, the Brand manufacturer has an equity ownership in the generic manufacturer or the Brand Name manufacturer shares in the profits during this period through a licensing agreement. Invoice pricing is not generally decreased by more than 20 – 25% than the Branded product during this period. Therefore, an FUL price should not be

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permitted until at least 2, or preferably 3 manufacturers make it available and affect market-place pricing.

Inclusion of Administration Fees or Service Fees paid to Wholesalers, PBM's or HMO's:
These fees are not available to the Retail Pharmacy Trade and should be excluded from the calculation. They are kept by the above entities and have no affect to invoice pricing to Retail Pharmacy. If you actually feel that these fees are more than nominal, then further legislation in the future should address this. It should not be even considered at this time.

Nominal Pricing:
This pricing is also not available to the Retail Pharmacy Trade and should be excluded from any calculations.

Use of pricing services in any way to determine FUL's:
We have seen over the past 3 years when most manufacturers stopped supplying AWP's to the pricing services because of multiple lawsuits that all pricing services are not the same. We have seen some able to update prices in a timely manner, while others take 60 – 90 days to update price changes. Using the "lowest price" from these pricing services would just mean that you would be using outdated information in many cases. This should be done internally in a timely manner and the "slow poke" should be excluded entirely.

Use of 9 digits NDC versus the 11 digits NDC:
Every stores inventory of a product is determined by actual usage of a product. In these times, proper control of inventory is very important to a stores bottom line. Therefore, since you agree that keeping the 11 digits NDC is no more work than keeping the 9 digits, I would suggest that the 11 digits be used to allow for the difference in the popularity of a drug in different areas of the country.

Outlier Price:
Because a manufacturer stops manufacturing a product does not mean that the pricing services remove the product. In fact, it remains for quite some time. There are many instances where many manufacturers decide to stop manufacturing a drug and the price from the remaining manufacturers increase sharply in price. Your guidelines do not consider this, and this has become a very common practice. Under your guidelines, it could take well over 90 days for you to catch up while stores would lose money filling these prescriptions.
What must be done is for your department to set up a process whereby pharmacies can fill out a form showing that a product is not available from their distributors at the price you are paying. This information can be verified quickly and pricing changed in a timely manner. We presently have a program in affect in Pennsylvania with most of the Third Party Plans, including Medicaid Programs and Part D Programs, and have had great success.

Savings Estimates developed by the Office of the Actuary in CMS:
In this section you mention the impact on just 3 types of small businesses, & they are (1) small pharmaceutical companies participating in the Medicaid Drug Rebate Program, (2) small retail pharmacies & (3) physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid for physician administered drugs.
It should be noted that while these proposed rules will affect all of Pharmacy, including the large Chains, no consideration is given to these small retail pharmacies that have increased their generic utilization to over 55% and whose business is much more dependent on prescription sales than the larger chains.
In the summary of this section, your people say this will only result in an overall 1% decrease. From what I have seen and heard from others with much more information in hand, AMP pricing will decrease reimbursement by $3.00 to $4.00 per prescription which will decrease gross profits by approximately 15 – 20% for an industry that is seeing its profits decreasing yearly.
The loss of access by the consumer when more Independents close their doors CANNOT be picked up by the Chains or mail-order who do not offer the personal services provided by Independent Pharmacy (counseling, pick-up & delivery, house charges, third party administrative help, and the knowledge of their patient needs to name just a few).

Summary:
It seems that Pharmacy is the easiest group to attack and from which to take money back. Federal Antitrust laws prevent us from working together so what can a "small" Independent do to fight back with any success? Medicare Part D has placed such a burden on Pharmacy that only a very few have the time to read over these 150 pages & express their concerns. I hope my comments and suggestions are considered.

Suggestions:
Include the Pharmacy Profession in your meetings and allow our National Groups to sit in and express their feelings at your meetings before a proposed ruling is sent out for just a 60 day comment period. Include managers of Chain Stores & owners of Independent Stores that "live" the day-to-day operations of a pharmacy.

Do your "Cost of filling an Rx" surveys and abide by their results. Include input from the Pharmacy Community & I am sure your results will not differ from those surveys already completed by CPA's, Schools of Pharmacy & State Agencies.

With Gross Profits so low in this industry, a fair Federally Mandated Profession Fee must be included in your final rulings if you now expect to receive acquisition costs. Do the calculation on a drug where a 30 day supply may cost 50 cents, $5, $10 etc. One price does not fit in Pharmacy, never did & never will. At least a Minimum Professional Fee must be mandated that will allow stores some type of Return on Investment.

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Include Wholesaler & Distributors Mark-Ups in your calculations.

Insist that your employees spend a full day in a Pharmacy before they write up the final rules.

Members of PHRMA are not affected by these rulings while their products still account for **85%** of your drug costs. Have them explain the much lower pricing they offer other countries. Have them explain why they spend more on TV advertising than they do on Research & Development.

A 5% decrease in pricing from PHRMA will save much more than $8.4 Billion.

Finally:

It is time someone in the government gets the courage to go after the real money to be found in the huge profit margins of big PHRMA and the PBM's. Take any more from Community Pharmacy and there will be no next generation of patient and service oriented independent pharmacist/owners since they will no longer be able to make a decent living. That would indeed be a tragedy and very short sighted on CMS's part. Pharmacists are the most respected and easily accessible health care professionals. The patient medication counseling they now provide saves CMS million, if not billions of dollars annually in hospital and related expenses that do NOT occur due to the influence they have on patients taking medication correctly. These CMS proposals will put many independent pharmacy owners out of business and the positive influence they have on patient outcomes will disappear. Any savings CMS thinks it will gain will be far outweighed amid skyrocketing costs in other areas of healthcare.
This administration has targeted community pharmacy for 90% of the Medicaid cuts-although those expenses account for only 2% of the Medicaid budget- in the form of reduced payments for generics.

I thank you for this opportunity to express my concerns:

Mel Brodsky R.Ph.
CEO

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Fino's Pharmacy

PRESCRIPTION DRUGGIST

32 N. Main Street — Phones: 655-1489 — 655-1480

Pittston, Pa. - 18640

January 16, 2007

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

Dear Ms. Leslie V. Norwalk, Esq.

I am taking this opportunity to comment on the proposed rule changes that will implement the provisions of the Deficit Reduction act of 2005 (DRA).

The attached pages contain my specific comments.

Allowing each State to set Professional Fees:
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We thank you for this opportunity to express my concerns.

Yours truly,

Vincent J. Peck R. Ph.

Fino's Pharmacy

CSL Behring
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901

Tel 610 878 4000
www.cslbehring.com

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CSL Behring

January 12, 2007

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

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

Dear Administrator Norwalk:

CSL Behring is a leading researcher and manufacturer of life-saving biotherapeutics including immune globulins, which are used in treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or through the development of recombinant DNA technology.

Thank you for allowing ZLB Behring the opportunity to comment on the proposed rule implementing provisions of the Deficit Reduction Act of 2005. CSL Behring does not have comment with regard to the proposed calculation requirements for Average Manufacturers Price (AMP) and Best Price. However, we desire to comment on a policy that CMS did not mention within the proposed rule, but one that we feel must be referenced in the final rule in order to preserve access to care for a very small but specific Medicaid population.

CSL Behring asks CMS to incorporate a provision within the final rule referencing the need for state Medicaids to adopt a furnishing fee for blood clotting factors in the form of a separate payment added into the determined payment rates. This provision should be modeled on current Medicare law that has preserved patient access and allowed people with bleeding disorders the ability to obtain their blood clotting factor. CSL Behring believes such a reference to the Medicare provision in the final rule will provide proper guidance for state Medicaid programs utilizing AMP figures to determine Medicaid reimbursement rates. Such a provision will also allow Medicaid programs to recognize the unique attributes associated with the administration and utilization of blood clotting factors; as Medicare has.

Medicare Precedent for Blood Clotting Factor Furnishing Fee

The Medicare provision can be found at Section 303 (e)(1) of the Medicare Modernization Act (PL 108-173) that created a furnishing fee for blood clotting factor reimbursement under the Medicare program. The statute provides the clear rationale of the additional furnishing fee and states as follows:

> *In the case of clotting factors furnished on or after January 1, 2005, the Secretary shall after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled 'Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost', provide for a separate payment, to the entity which furnishes to the patient blood clotting factor, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:*
>
> *(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.*
>
> (ii) *Ancillary supplies and patient training necessary for the self-administration of such factors.*

For blood clotting factors furnished in 2006 and beyond, the statute requires that the separate payment under Medicare is to be equal to that of the previous year in addition to the percentage increase in the consumer price index for medical care for the 12-month period ending in June of the previous year.

Medicare published an initial blood clotting factor furnishing fee based solely on the Comptroller General report in the 2005 Physician Fee Schedule proposed rule, but increased the figure for the final rule, based on dialogue with medical providers of blood clotting factor and data tabulated by the Lewin Group. As a result, CMS determined the per unit additional payment for blood clotting factor under Medicare as follows:

2005: $0.140 per unit
2006: $0.146 per unit
2007: $0.152 per unit

These separate payments apply for each class of blood clotting factors and have been incorporated into the Medicare reimbursement rate for each class.

CSL Behring

Thank you for your consideration and attention to this matter. If there are any questions or if I may be of assistance, please feel free to contact me directly at 610-878-4583 or Patrick Collins as 610-878-4311.

Sincerely,

Dennis Jackman
Senior Vice President, Public Affairs

Same Principles Apply for Medicaid Reimbursement

The rationale for providing the additional furnishing fee for blood clotting factors under Medicare also applies for Medicaid. Providing blood clotting factors for treatment requires the same services, regardless of the individual's specific type of insurance. Without reference to the need for such a furnishing fee under Medicaid, the danger exists that states will incorporate the AMP methodology for reimbursement without a furnishing fee like that in Medicare. This would in turn create a substantial discrepancy between Medicare and Medicaid reimbursement in addition to creating access problems for Medicaid beneficiaries with bleeding disorders.

Without inclusion of a Medicaid furnishing fee for blood clotting factors, patients in need of this life-saving therapy will undoubtedly face access difficulties, as reimbursement will not reflect the true costs of providing this therapy. If reimbursement is inadequate, providers will have great difficulty being able to afford and supply blood clotting factor; thus, creating a situation where the individual may not be able to obtain the therapy to treat a bleed. The furnishing fee provision under Medicare has served to prevent such issues and has maintained both access to care and an appropriate medical standard of quality care. It is rational and consistent with established CMS and congressional policy to incorporate such a provision under Medicaid, especially if AMP is to be used in determining reimbursement payment rates.

There are approximately 6000 Medicaid beneficiaries nationally with hemophilia who rely on blood clotting factors. Unlike other therapies with mass utilization, hemophilia is a rare disorder, so incorporating a Medicaid furnishing fee should not impose substantial costs. The Congress and CMS have put in place a precedent under the Medicare program establishing a separate payment in the form of a furnishing fee that has been an unequivocal success in maintaining access to therapy. CSL Behring urges CMS to consider referencing a furnishing fee for blood clotting factors in the Medicaid proposed rule in order to provide state Medicaid programs with proper guidance in order to preserve access to high quality services for these beneficiaries.

NORTH MISSISSIPPI
MEDICAL CENTER

January 26, 2007

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

To Whom It May Concern:

On behalf of North Mississippi Medical Center (NMMC), I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. NMMC is a 650 bed hospital located in Tupelo, MS, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. If the NDC requirement was expanded to hospital Medicaid claims for drugs, NMMC's Outpatient Infusion Department would be burdened with new system developments which may interfere with patient access and care. NMMC's Outpatient Infusion treats 1,300 patients and has experienced continued growth over the last year. Business success and patient service could be disturbed by unnecessary change to work processes.

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

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. NMMC provides charity care and medications to over 4,000 patients annually during their stay in the hospital. The loss of nominal pricing contracts in our non-340B parts of the hospital would be devastating to the amount of service we could continue to provide.

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

Sincerely,

Harold Kornfuhrer, B.S.
Director of Pharmacy Services
North Mississippi Medical Center

4-1

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015
2-17-07

To Whom It May Concern:

On behalf of myself, working at Touro Infirmary, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Touro Infirmary is a 350 bed hospital located in New Orleans that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. The administrative burden on this already busy, heavily burdened institution post-Katrina. Touro Infirmary operates both an inpatient and outpatient pharmacy. The insertion of the actual NDC numbers in all Medicaid claims would add another 30 minutes per drug item per month or approximately $12,000 of technician time and $22,000 of pharmacist time to verify the accuracy of the NDC information. This would take valuable clinical time with patients away from pharmacists which help control drug cost through education of patients and providers. In addition, much of the costs savings realized through the discounted 340B program, enable the institution to serve as a low cost provider for indigent and under served populations of New Orleans. The moneys and time lost would not out weigh the services passed on to these patient populations. Thus, it would likely be of little benefit to participate in the 340B savings programs, clinical services and care to the underserved of New Orleans would be cut.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. Though the hospital where I practice has not fully implemented or taken advantage of the 340B programs for the hospital, future endeavors in this arena would not be pursued. Proposed services to oncology out patients, such clinical pharmacists and admixture specific for that area would not be implemented. Cost-reduction strategies through cognitive services and implementing protocols would certainly be lost. Current estimates are between $100,000 and $150,000 per year.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our

hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. Currently serving as the main institution for care patients in New Orleans (due to the down-sizing of Tulane and University Hospitals and closure of Charity Hospital) the impact on Touro Infirmary and its indigent patients of increased outpatient drug prices that would result in higher costs and less uncompensated care provided if higher AMP figures were to be used for calculating 340B prices and nominal pricing contracts lost.

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

Sincerely,

Helen M Calmes, PharmD, MBA
Clinical Pharmacy Manager
Touro Infirmary

5

Bayer HealthCare

February 20, 2007

Hand-Delivery

FEB 20 2007

Leslie V. Norwalk, Esquire
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Acting Administrator Norwalk:

Bayer HealthCare LLC

400 Morgan Lane
West Haven, CT 06516

Phone: 203-812-2000

Bayer HealthCare LLC ("Bayer") is pleased to submit the following comments in response to the proposed treatment of prescription drugs under the Medicaid Drug Rebate Program ("Proposed Rule").[1] For over 100 years, Bayer has produced high-quality drugs and biologics that have helped patients lead healthier lives. We fully support the Center for Medicare and Medicaid Services ("CMS" or the "Agency") efforts in the Proposed Rule to further clarify the calculation of both Average Manufacturer Price ("AMP") and Best Price ("BP"). Bayer is happy to offer the following comments based on our rich experience.

We are encouraged by several components of the Proposed Rule. We do have a number of serious concerns, however, with a number of important aspects of the Proposed Rule.

In brief, Bayer offers the following comments for consideration:

- We support only prospective application of the Final Rule following its publication and a reasonable period for implementation thereafter.
- We strongly oppose the significant policy change with regard to sales to long-term care ("LTC")

[1] Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77,174 (proposed Dec. 22, 2006)(to be codified at 42 C.F.R. pt. 447).

pharmacies, and we encourage CMS to continue its long-standing policy of including these sales in the calculation of AMP.

- Bayer generally supports the Agency's proposed treatment of sales to pharmacy benefit managers ("PBMs"), health maintenance organizations/managed care organizations ("HMOs/MCOs"), and Medicare Part D.

- We must disagree strongly with CMS' proposed treatment of Medicaid transactions.

- We cannot support the proposal regarding bundling because the Proposed Rule lacks sufficient detail to provide us notice or an opportunity for comment on the proposal.

- Bayer agrees with the proposed treatment of the prompt pay discount and returns. Both proposals take a practical approach.

- We are concerned by CMS' possible articulation of a new BP standard that would be fundamentally inconsistent with the Medicaid statute. We fear that some could interpret the proposal as requiring the aggregation of PBM concessions with concessions paid to customers of the PBM—even when a manufacturer does not know that the PBM has passed its concessions on to that customer.

- Bayer urges CMS to abandon its proposed treatment of manufacturer coupons. Requiring disparate treatment for substantively indistinguishable transactions will yield arbitrary results.

- We encourage the Agency to add further clarity to the proposed definitions of "single source drug" by specifically accounting for biologicals. We also urge you to clarify the prospective nature of the proposed definition of "physician-administered drug."

- In terms of manufacturer reporting obligations, we offer comments regarding the definition of "adequate documentation," reporting frequency, smoothing methodologies, and the restatement of base date AMP.

- Lastly, we offer comments on the survey of retail prices, future clarifications, and collection of information requirements.

Bayer thanks CMS in advance considering our comments on these issues, which we discuss in detail below.

I. Introductory Issues

Before we address a myriad of issues related specifically to AMP and BP calculations, we want to discuss two fundamental issues that pervade the Proposed Rule and apply to all aspects of our comments—the way the Final Rule will apply and the way the Proposed Rule relies on recommendations promulgated by the United States Department of Health and Human Services Office of the Inspector General ("OIG").

A. Prospective Application

We urge CMS to state clearly its intent that the Final Rule will only apply prospectively. Bayer understands that a few analysts are concerned that the Proposed Rule may be misinterpreted as having a potentially retroactive impact with respect to its AMP and BP elements not mandated by the Deficit Reduction Act of 2005 ("DRA").[2] We do not believe that CMS contemplated such an application. Nor do we believe that CMS could lawfully apply this Rule retroactively.

It is a well-settled principle of regulatory construction that for a provision to have retroactive application, the requirement must be explicitly and unmistakably set forth. Here, CMS simply has not made it clear that it intends for the Proposed Rule to have retroactive application. Moreover, even if CMS were to state such an

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[2] Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (codified as amended in scattered sections of 42 U.S.C.).

intent, we believe that the Administrative Procedures Act ("APA")[3] would prohibit this approach.[4]

The Proposed Rule contains significant, substantive changes to longstanding practices and guidance regarding the calculation of AMP and BP. It is clear that the Proposed Rule contains numerous examples of entirely new guidance where manufacturers had previously been permitted to make reasonable assumptions.[5] We offer two examples where CMS clearly overturns long-standing policies which manufacturers have relied on: treatment of sales to SPAPs and LTC pharmacies.

The proposed treatment of sales to LTC pharmacies and sales related to SPAPs exemplify the fact that the APA would be violated if the Proposed Rule were applied retroactively. Both proposals represent a departure from historical written guidance in the Medicaid Drug Rebate Program Releases.[6] In both of these cases, CMS fails to make clear that proposed policies will only apply prospectively. To resolve any doubts, we urge CMS to directly address the issue of prospective versus retroactive application in the Final Rule.

The Proposed Rule often represents a substantive change in policy and the applicable guidance. This is true even where it does not represent a reversal in prior, specific guidance about the treatment of a particular item. The Agency has directed manufacturers to make and act in accordance with reasonable assumptions in a variety of areas. The Medicaid Drug Rebate Agreement expressly permits manufacturers to make reasonable assumptions.[7] Historically, in many areas where CMS has not issued specific guidance, manufacturers have in fact made and relied on

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[3] Administrative Procedures Act, 5 U.S.C. § 500 et. esq. (2007).

[4] *See* Coalition for Common Sense in Gov't Procurement v. Sec'y of Department of Veterans Affairs, 464 F.3d 1306, 1308-09 (Fed. Cir. 2006) *citing* Paralyzed Veterans of America v. West, 138 F.3d 1434, 1436 (Fed. Cir. 1998).

[5] We appreciate that the elements of the Proposed Rule mandated by the DRA, particularly the change in the treatment of prompt pay discounts, take effect as of the effective dates listed in the DRA.

[6] *See* Medicaid Drug Rebate Program Release No. 29 (June 2, 1997).

[7] Center for Medicaid Services, Medicaid Drug Rebate Agreement § II(i), http://www.cms.hhs.gov/MedicaidDrugRebateProgram/14_NationalDrugRebateAgreement.asp.

reasonable assumptions. Retroactive application of the Proposed Rule would unfairly penalize manufacturers' good faith efforts to comply with requirements of the Medicaid program and for their reliance on the reasonable assumptions that they have made, as directed by CMS.

There are also a number of serious practical limitations which dictate that the Final Rule should not be applied retroactively. For example, systems limitations would make it difficult, and, in many cases, impossible, for manufacturers to recalculate AMPs or BPs for prior quarters under a new methodology. The AMP calculation, in particular, is operationally complex. It often requires the gathering of detailed data sets and the use of sophisticated information systems.

Even where recalculation is feasible, it would likely place a significant administrative burden on manufacturers as proposed. We believe that recalculation may simply no longer be possible in many cases. In fact, manufacturers or their customers may not have the necessary data to revise retrospectively their calculations based on the numerous changes in price reporting guidance contained in the Proposed Rule. The lack of data and other operational issues would impose a tremendous, perhaps insurmountable, burden on many manufacturers. These significant operational obstacles weigh in favor of prospective application.

As described above, the APA requires prospective application. Retroactive application would create a host of serious problems. Moreover, we believe a Final Rule with retrospective application would be void under the APA because of its substantial departure from the preexisting requirements of the Proposed Rule. We urge CMS to clearly state that the Final Rule will only apply prospectively.

B. Reliance on OIG Guidance

The treatment of prescription drugs under the Medicaid program (the "Program") presents complex issues, and we commend CMS' efforts to clarify the rules governing many aspects of the Program. Since the Program's inception, CMS has developed significant expertise with regard to the products provided. The Agency is well aware of industry's attempts to secure clarification on a broad array of issues over the years.

Throughout the Proposed Rule, CMS discusses recommendations made by the OIG. We appreciate that the Act requires the Secretary to consider the OIG's recommendations regarding prescription drugs under the Medicaid Program. Nevertheless, we caution CMS to weigh carefully the OIG's recommendations against the Agency's own significant expertise in this area.

Because the OIG lacks a working understanding of the history of many of these issues, we fear its recommendations could lead to the inconsistent treatment of important issues related to the Program. While we appreciate the OIG's comments on the Program, we believe that those comments must be tempered by acknowledging the inherent limitations of policy analysis offered by an enforcement agency which does not possess responsibility for managing the Program.

Clear, understandable price reporting guidance is pivotal. We cannot overstate the importance of practical and consistent direction. We fear that the OIG may overlook critical policy considerations because it lacks CMS' operational perspective. Where inconsistent policy recommendations arise from OIG recommendations, we urge CMS to favor its own, seasoned conclusions and issue clear guidance based on that experience.

II. Determination of AMP (Section 447.504)

We commend CMS for articulating the rationale behind its proposals, and we appreciate the description of a particular test, where applicable. For example, in its definition of "retail pharmacy class of trade," CMS seems to articulate an assessment based on whether or not sales are available to the general public.[8] We appreciate this effort to describe the history and development of the Agency's thinking. However, we are concerned the test, as articulated, lacks sufficient clarity. We need a better understanding of how broadly the Agency defines the term before we can fully appreciate the application of this test. It is particularly unclear whether availability to the general public turns on the number of affected patients and purchases or on the means of delivery. We can

[8] 71 Fed. Reg. at 77,178.

conceive of circumstances where one but not both apply. In light of this ambiguity, our comments, when possible, attempt to address the basis for the Agency's proposal.

Bayer believes that the Proposed Rule represents an important and necessary step forward in standardizing AMP calculations. However, in our comments below, we urge CMS to significantly refine its guidance. Our first set of comments on this topic discusses issues related to the following specific classes of trade or types of customers: PBM, LTC pharmacy, mail order pharmacy, HMO, Medicaid, Medicare Part D, and direct patient sales. Second, we address issues that could potentially impact a variety of customer types. These comments focus on administrative fees, prompt pay discounts, bundling, returned goods, and the definition of "adequate documentation."

A. Issues Related to Specific Customer Types

The DRA directed the Secretary to issue a formal regulation clarifying the requirements for, and the manner in which, AMP is determined.[9] CMS defines AMP in the Proposed Rule 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."[10] The Proposed Rule goes on to define "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."[11]

This term is further defined in the preamble, stating that "the retail pharmacy class of trade means that sector of the drug marketplace,

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[9] *Supra* note 2 at § 6001(c)(3).

[10] 71 Fed. Reg. at 77,196 (proposed to be codified at 42 C.F.R. § 447.504(a)).

[11] *Id.* (proposed to be codified at 42 C.F.R. § 447.504(e)).

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."[12]

We offer the following comments specific to LTC pharmacy, PBM, mail order pharmacy, HMO, Medicaid, Medicare Part D, and direct patient sales.

1. LTC Pharmacy Sales (Section 447.504(h)(6))

CMS proposes to exclude from AMP the prices of sales to nursing home LTC pharmacies.[13] The Proposed Rule states that these sales fall outside the retail pharmacy class of trade.[14] However, we believe this proposal is completely inconsistent with CMS guidance issued to date, and we are greatly concerned by this proposed substantive policy change. We disagree with the rationale CMS articulates for excluding such sales, and respectfully request that LTC pharmacy sales continue to be included in the AMP calculation.

We understand that one argument in favor of their exclusion rests on the belief of the retail pharmacy industry that LTC pharmacies, like mail order pharmacies, pay less for drugs than retail pharmacies.[15] We appreciate that the proposed definition is designed to address the retail pharmacy industry's contentions that an AMP used for reimbursement to retail pharmacies should only reflect prices of sales to those pharmacies which dispense drugs to the general public.[16] An end's driven analysis of this, or any other, class of trade issue will not yield an appropriate result.

Important Medicaid policy clearly mandates inclusion of LTC pharmacy transactions. First, because LTC pharmacy transactions are a significant portion of the market for many drugs, the exclusion of those transactions from AMP would yield inaccurate and misleading AMPs. To begin, many LTC residents are dual-eligibles. It seems inconsistent to propose excluding LTC sales while at the same time proposing to include sales to Medicare Part D. We

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[12] *Id.* at 77,178.
[13] *See id.* at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(h)(6)).
[14] *Id.*
[15] *See* 71 Fed. Reg. at 77,178.
[16] *Id.*

are unclear as to how these customers differ under the general public test as articulated. Moreover, because for so many drugs LTC pharmacy transactions are a significant portion of their market, the exclusion of those transactions from AMP would yield inaccurate and misleading AMPs.

Second, the costs of changing the current policy that includes LTC pharmacy transactions would require substantial changes in systems, policies, procedures, and data links that would more than offset the perceived benefit in "simplifying" the AMP calculation. Thus, manufacturers and others have signed agreements in reliance on clear and unambiguous statements of the applicable price reporting rules. It is simply unfair to change the underlying rules after contracts have been entered into based on that guidance. The purpose of the rule contemplated by Congress was to address unanswered and ambiguous reporting issues in order to create greater confidence in the system, not to reverse policy on clearly established points and further undermine confidence in that system.

In conclusion, we oppose the exclusion of LTC prices from AMP and encourage CMS to reverse its position on sales to LTC pharmacies in the Final Rule. Bayer believes any departure from current policy in this area is unwarranted.

2. Mail Order Pharmacy Sales (Section 447.504(g)(9))

Bayer supports CMS' decision to maintain the existing policy to include sales and price concessions to mail order pharmacies in the AMP calculation.[17] We agree with CMS that mail order pharmacies "are simply another form of how drugs enter into the retail pharmacy class of trade."[18] The health care delivery system continues to evolve. This is evidenced by the fact that neighborhood pharmacies are no longer the only means for patients to obtain prescriptions. Patients may choose to obtain their prescriptions from mail order pharmacies for a variety of reasons. However, the retail nature of the sale to that patient is no different if the prescription is picked up at the pharmacy counter or if it is shipped to his or her mailbox. We appreciate that CMS recognizes this point.

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[17] *See id.* at 77,178.

[18] *See id.*

3. PBM Sales (Section 447.504(g)(6))

In the Proposed Rule, CMS calls for the inclusion of discounts, rebates, and other price concessions to PBMs associated with the retail pharmacy class of trade in the calculation of AMP.[19] We urge CMS to clarify in the Final Rule that it will permit manufacturers to make and rely on appropriate reasonable assumptions regarding PBM sales because manufacturers face operational challenges in collecting data related to non-mail order sales.

We thank CMS for its discussion of the price reporting challenges associated with PBM sales in the preamble to the Proposed Rule, and for its general understanding of the substantial difficulties presented in obtaining and analyzing data from PBMs. However, we believe that CMS does not fully appreciate the extent of the problem. Proposing to require that manufacturers must specifically link a PBM concession to a retail class of trade customer demonstrates CMS' lack of comprehensive understanding. Below, we examine the difficulties associated with PBM data.

It is often impractical, if not impossible, for a manufacturer to obtain precise retail and non-retail analysis on a PBM's non-mail order sales. Of course, this varies to some extent on a PBM's system and data capabilities and what level of data sharing is required under their established contracts. Some PBMs may provide data that may allow some manufacturers to segregate their non-mail order sales data into retail and non-retail sales under some circumstances.

In has been our experience, however, that this is not always the case for all sales. In fact, many PBMs are unwilling or unable to provide this data to manufacturers. Some PBMs simply do not compile such data. Due to varying levels of data availability, it is crucial that manufacturers maintain the flexibility to make reasonable assumptions in the determination of the non-retail class of trade. To be meaningful, CMS must allow PBM price concessions to reduce AMP as determined through the application of reasonable assumptions.

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[19] *See id.* at 77,196-97 (proposed to be codified at 42 C.F.R. § 447.504(g)(6)).

Our price calculations are only as accurate as the data provided to us in the context of PBM sales. When data from the PBM is unavailable, or would be too costly to obtain or to analyze, manufacturers should be permitted to rely on representations made by the PBM regarding its customer mix. Manufacturers should be able to use this information to make reasonable assumptions regarding which sales are retail and which sales are not. Further, if data from a PBM permits analysis for some proportion of sales, but not all sales, a reasonable assumption should be permitted to allow the rates of retail to total sales to be applied to those sales for which data is unavailable.

The new certification requirement makes the need for specific guidance authorizing and permitting the use of reasonable assumptions all too clear. CMS should not hold manufacturers accountable in the event of errors in the PBM data. Where the PBM has represented in writing that the data is true and correct to the best of its knowledge and when a manufacturer acts in good faith, it does not stand to reason that CMS should hold accountable either the manufacturer or the PBM for any mistakes or errors in that data.

Additionally, manufacturers should be permitted to make reasonable assumptions based on data from one PBM and apply it to another similarly-situated PBM. In the Final Rule, we urge CMS to recognize appropriately the operational challenges manufacturers face in collecting data related to non-mail order sales. We believe that permitting manufacturers to make appropriate, reasonable assumptions and allowing them to rely upon those assumptions is the best solution.

4. HMO/MCO Sales (Section 447.504(h)(5))

Bayer is pleased that CMS included MCOs in its definition of HMOs, which the statute specifically excludes in section 1927 of the Act.[20] The managed care model has continued to mature since the Program's inception. Although staff model HMOs were considered the cornerstone of managed care at one time, that is no longer the case. Our health care delivery system has also come to embrace preferred provider organizations and point of service plans,

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[20] *See* 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 447.505(b))

as well. It is important to recognize a broad assortment of managed care models that accurately reflect the care provided to beneficiaries and remain consistent with the spirit of the statute. Thus, we agree with the Agency's proposal to permit manufacturers to include all managed care entities in its proposed definition of "provider."[21]

Consistent with our arguments above in our discussion of PBM concessions, Bayer urges CMS to recognize an exception to the exclusion of managed care sales where a manufacturers claims PBM concessions. It is a near certainty that those concessions will be related to managed care transactions. It would be illogical to include a managed care concession, but exclude the underlying sale. Depending on whether manufacturers have access to end-customer data from PBMs, this type of flexible treatment of managed care and PBM transactions would provide manufacturers with reasonable alternative approaches.

5. Medicaid Sales (Section 447.504(g)(12))

CMS proposes to include Medicaid prices in the calculation of AMP.[22] Bayer is concerned by this proposal because it would introduce dissimilar treatment of the same transaction for AMP and BP purposes. We believe that the proposal would create a real potential for inadvertent errors stemming from this incongruent treatment. As such, we respectfully request that CMS exclude Medicaid sales from the AMP calculation.

By including Medicaid prices in AMP, it appears that this proposal would disconnect rebates from their underlying sales. We fear that doing so would artificially skew AMP and would not reflect the price actually realized by the manufacturer. Because the statute prohibits manufacturers from including part of the rebate, it is only fair to exclude both the rebate and the underlying sale from AMP calculations.

Congress expressly exempted Medicaid sales from BP.[23] Doing so encourages manufacturers to provide the lowest possible prices to government health care programs. Given the statutory

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[21] *See id.*

[22] *See id.* (proposed to be codified at 42 C.F.R. § 447.504(g)(12)).

[23] 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I)(2007).

exclusion of Medicaid sales from BP, it follows that CMS should exercise its discretion by excluding them from AMP as well. This change would achieve consistency in AMP and BP calculations, which has significant advantages. Symmetrical treatment of these transactions noticeably reduces the difficulty involved in these already complex calculations.

The proposed disparate treatment for AMP and BP purposes is particularly troubling. It would seem to increase the administrative complexity without any real benefit. Accordingly, we urge CMS to exclude Medicaid sales from AMP.

6. Part D Sales (Section 447.504(g)(12))

We generally support the inclusion of Medicare Part D sales in the AMP calculation.[24] Bayer applauds CMS for articulating consistent proposals for Part D and PBM sales. Generally speaking, Part D sales overlap significantly with PBM sales. We are pleased that CMS recognizes the need for similar treatment.

That being said, Bayer shares the same concerns for Part D sales that we expressed above regarding the price reporting challenges associated with PBM sales. We hope that CMS will likewise appreciate the substantial difficulties posed in obtaining and analyzing data from Part D plans ("PDPs"), Medicare-Advantage PDPs ("MA-PDPs"), and qualified retiree prescription drug plans for covered Part D drugs. Here again our ability to obtain data will rely on a plan's system and data capabilities and what level of data sharing is required under their established contracts. Due to the varying availability of data, the flexibility to make reasonable assumptions in this regard is critical.

While Bayer supports the proposal to include Part D sales in AMP, we hope that CMS will recognize appropriately in the Final Rule the operational challenges manufacturers face in collecting data. Based on those challenges, we urge CMS to allow manufacturers to make and rely upon appropriate reasonable assumptions when including Part D sales in AMP.

7. Direct Patient Sales (Section 447.504(g)(7))

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[24] *See* 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(g)(12)).

CMS finds that direct sales to patients "are usually for specialty drugs through a direct distribution arrangement, where the manufacturer retains ownership of the drug and pays either an administrative or service fee to a third party..." [25] As a result, the Agency proposes to include direct sales to patients in the calculation of AMP.[26] Bayer strongly opposes this proposal to include direct sales to patients in the calculation of AMP because there simply is no retail class of trade transaction in the case of a direct shipment to a patient.

It defies reason that CMS could consider a sale to a particular, identified patient a "wholesale" transaction. The statutory language simply fails to support the proposed construction, even with the broad definition of a "wholesaler" in the Medicaid Rebate Agreement.[27] As Bayer has stated to CMS on numerous occasions, if a patient is considered a "wholesaler," the clear distinction contemplated by the statute between a "wholesaler," on the one hand, and the "retail class of trade," on the other, would be eradicated. It defies reason that CMS could consider a sale to patients, and similarly, a sale to physicians of product earmarked for an individual patient, a sale to a "wholesaler." These drugs are not offered or intended for the general public.

When a manufacturer makes a patient-specific direct shipment, there simply is no connection to the retail class of trade the product shipped in. These are sales directly from a manufacturer to a specific patient. Manufacturers often have varying means of delivery of their product to these specific patients. For example, a manufacturer may ship directly from its manufacturing facility to a patient. Additionally, a manufacturer may choose to send their product, on a patient-specific basis, through a specialty pharmacy that does not take title to the drugs and rather serves as a delivery point for the patient. Manufacturers may also engage in numerous other methods of delivering patient-specific product. Regardless, it is always true for direct patient sales that the product is marked for a specific patient and never available to any member of the general public.

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[25] *See id.* at 77,180.

[26] *See id.* at 77,191 (proposed to be codified at 42 C.F.R. § 447.504(g)(7)).

[27] *Supra* note 7 at § I(ee).

There are important policy considerations, particularly in the context of orphan drugs, which encourage manufacturers to engage in direct patient sales. For orphan drugs, these sales necessarily target small populations. These products are intended for one particular patient, and only that particular patient. Because the market for these products is so small, it is important that CMS policy encourages manufacturers to continue to engage in practices where the product follows the patient. CMS' proposal to include these sales in the calculation of AMP, we fear, would make it difficult for patients to reliably obtain access to life-saving therapies. The proposal unfairly penalizes manufacturers who elect for a non-traditional delivery method in the interest of best meeting patient needs.

Importantly, CMS has provided numerous pieces of guidance stating that manufacturers should exclude various direct items to patients in the calculation of AMP and other price reporting metrics. Indeed, historically, the idea that coupons designed to benefit patients should not have an effect on price reporting has to be based on the idea that the patient, and concessions offered to the patient, are distinct from those offered to others. The Agency has repeatedly discussed this concept in providing guidance to various program participants and repeats it to some extent in the Proposed Rule itself, for example, in the manufacturer coupon proposal.

CMS' proposed inclusion of direct patient sales in the calculation of AMP is simply not consistent with the statute or CMS' own previous guidance in this area. We urge the Agency to reverse its position in the Final Rule.

B. Issues Impacting Various Customer Types

Not every issue related to the definition of "retail pharmacy class of trade" can be linked to any single customer type. In this section, we discuss some issues which relate to a variety of our customers. Specifically, we address administrative fees, prompt pay discounts, bundling, returned goods, and the issue of "adequate documentation."

1. Administrative Fees and Service Fees (Section 447.504(h)(11))

The Agency proposes to exclude bona fide service fees from AMP but to include all other service fees.[28] Consistent with our comments concerning the 2007 Medicare Physician Fee Schedule Proposed Rule, we encourage CMS to rely upon the group purchasing organization ("GPO") safe harbor associated with the federal Anti-Kickback Statute ("AKS") as it defines which service fees qualify as bona fide.[29]

By virtue of the OIG's Guidance to Pharmaceutical Manufacturers,[30] PBM administrative fees have been analyzed by applying the GPO safe harbor to the AKS. Since at least that time, many manufacturers have used the AKS Safe Harbor to determine the appropriate treatment of administrative fees for price reporting purposes, whether paid to GPOs or to PBMs. For example, some manufacturers treat an administrative fee of 3 percent of the purchase price as a bona fide service fee and any administrative fees exceeding that amount, if any, as price concessions.

There is a clear benefit, both to the government and to manufacturers, of a consistent policy under both the AKS and the price reporting rules. Bayer believes that CMS should officially adopt this position as a price reporting rule. The Final Rule should state that an administrative fee meeting the requirements of the Safe Harbor does not act as a reduction in price for price reporting purposes. Specifically, we encourage CMS to adopt a definition of bona fide service fees in this context that is consistent with the AKS Safe Harbor.

We note that CMS is proposing to use the bona fide service fee test from the ASP guidance here in an AMP and BP context. In reality, the Proposed Rule would actually create a disconnect between the ASP practice and AMP and BP practice. As CMS stated in the 2007 Medicare Physician Fee Schedule Final Rule, manufacturers need not take administrative fees paid to GPOs or PBMs as a reduction to ASP, at least until additional guidance is issued, without regard to whether the bona fide service fee test was met.[31] It is of vital importance that CMS ensure consistency between

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[28] 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 504(h)(11)).
[29] *See e.g.* 42 C.F.R. § 1001.952(j)(2)(2006).
[30] *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003)
[31] 71 Fed. Reg. 69,624, 69,669 (December 1, 2006).

the ASP methodology and the AMP and BP methodologies to the fullest extent practicable. This will reduce the risk of inadvertent errors, increase transparency in the calculations, and reduce the huge systems, data, and calculation costs involved in implementing different, inconsistent approaches.

2. Bundled Items (Section 447.502)

Bundled price concessions are typically understood to be arrangements in which a purchaser's price for one or more drugs is contingent upon the purchase of other drugs or items. Because CMS has not provided prior guidance in the AMP context regarding the proper method to apportion price concessions across drugs that are sold under bundling arrangements, we thank CMS for its statement that it is considering providing guidance on the proper method to apportion price concessions among drugs sold under bundling arrangements. We believe this guidance could be most helpful in assisting manufacturers with this difficult price reporting issue.

Despite this, we do not believe that the Proposed Rule contains enough discussion of this issue to provide reasonable notice and an opportunity for comment. Bayer respectfully suggests that CMS provide some alternative mechanism or forum for manufacturers and other interested parties to have more substantial and more specific communication with the Agency on this important issue. The Proposed Rule does not provide enough detail to allow for us to provide meaningful comments. For any discussion to be helpful, the scenarios at issue must be clearly presented and CMS must specify the proposed treatment or alternative treatment.

Further, we were disappointed with the lack of meaningful detail in this proposal because it essentially mirrors the bundling proposal CMS articulated last year in the ASP context as part of the 2007 Medicare Physician Fee Schedule Proposed Rule.[32] After declining to proceed with the somewhat unspecific proposal in the 2007 Medicare Physician Fee Schedule Final Rule,[33] we were hopeful that the proposal here would be more precise and clear, but that is not the case. For instance, we are confused by the suggestion in the Proposed Rule that a bundle may consist of the same drug. We do

[32] 71 Fed. Reg. 48,982, 49,003-004 (August 22, 2005).
[33] *Supra* note 31.

not understand what the Agency is suggesting here or how this might alter price reporting obligations.

With that said, in general, any bundled relationship should have price reporting treatment that accurately reflects the value of the bundle to the products that are the subject of that bundle, and we support that policy. Given the proposal you have articulated, we cannot provide any additional comment at this time. We look forward to having an opportunity to comment on a more refined, more fully articulated proposal in the future.

3. Customary Prompt Pay Discounts

The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers,[34] but it does not define the term "customary prompt pay discount." CMS proposes to define a customary prompt pay discount as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date."[35] We appreciate CMS' clarification and proposed definition of customary prompt pay discounts, and Bayer wholeheartedly agrees with CMS' definition to include the prompt pay discount then in effect at the time of any AMP calculation.

While we fully agree with the proposed definition to include the prompt pay discount that is then prevailing at the time of any AMP calculation, Bayer hopes that CMS will take note of the significant administrative burdens associated with tracking these discounts on an individual basis. We urge CMS to allow manufacturers to make reasonable assumptions regarding whether or not customers take a prompt pay discount when offered in light of these burdens. In addition, we ask CMS to give manufacturers the discretion, as a practical matter, to make a reasonable assumption regarding these discounts.

4. Returned Goods (Section 447.504(h)(13))

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[34] *Supra* note 2 at § 6001 (c)(1).
[35] *See* 71 Fed. Reg. at 77,179.

CMS proposes to exclude goods returned in good faith from the calculation of AMP.[36] We understand that this exclusion is premised on the fact that manufacturers accept returned goods pursuant to established internal policies and not in a manner designed to manipulate the calculation of AMP. Bayer supports this conclusion, and we ask that CMS specify that acceptance of a return in accordance with a pre-established return policy will constitute a good faith return.[37]

Bayer advocates this proposal because of the administrative burdens associated with allocating the returned goods back to the reporting period in which they were sold. Also, it is important for CMS to treat returned goods consistently. Bayer is pleased to see CMS' proposal to similarly exclude goods returned in good faith from the calculation of AMP because the Medicare Part B program excludes returned goods from the calculation of ASP.

Additionally, we believe that CMS's treatment of the returns issue consistently under ASP and AMP and BP favors the consistent treatment of other issues. We note elsewhere in this various inconsistencies in CMS's current proposal for AMP and BP purposes and its previous guidance under the ASP methodology. In general, we urge consistency in the various calculations as the best way to achieve accuracy and predictability.

5. Definition of "Adequate Documentation" (Section 447.504(g)(1))

CMS includes in AMP all sales to wholesalers except for those sales that can be identified with "adequate documentation" as being subsequently sold to any excluded entity.[38] We were disappointed that CMS provides no further clarification in the preamble as to what it means by the term "adequate documentation."

We hope that CMS will make clear in the Final Rule that manufacturers may rely on reasonable assumptions in determining what constitutes adequate documentation. For Bayer and other manufacturers this clarification is critical to comply with the adequate

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[36] *See id.* at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(h)(16)).
[37] *See id.* at 77,181.
[38] *See id.* at 77,196 (proposed to be codified at 42 C.F.R. § 504(g)(1)).

documentation requirement. This would be particularly helpful in light of the certification requirements now attached to manufacturer reporting. Because manufacturers must certify to the accuracy in price reporting, it would be fundamentally unfair to require them to do so when the accuracy of the prices reported may be subject to later criticism based on the adequacy of the underlying supporting documentation. This is particularly troubling when CMS has provided no guidance as to what constitutes sufficient documentation.

In order to provide sufficient guidance, CMS would have to address a variety of the issues in price reporting which would likely vary by item based on the nature of the documentation. We do not believe that CMS is in a position to supply specific guidance on the quality and the quantity of the documentation required in all of these instances. Thus, we think that an explicit recognition of the ability to make reasonable assumptions is the fairest approach. Moreover, this approach would be entirely consistent with other circumstances where CMS has not been able to provide specific guidance.

III. Determination of BP

The Proposed Rule clarifies the definition of BP to include the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application ("NDA") approved under section 505(c) of the Federal Food, Drug and Cosmetic Act ("FFDCA").[39] CMS proposes to clarify that BP is the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed.[40]

We appreciate CMS' additional guidance on the definition of BP. In our comments below, however, we want to address several important issues related to PBM concessions and manufacturer coupons.

A. PBM Concessions (Section 447.505(b)(2))

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[39] *See id.* at 77,197 (proposed to be codified at 42 C.F.R. § 447.505(a)).
[40] *See* 71 Fed. Reg. at 77,197-98.

Although we applaud CMS' attempt to clarify the BP calculation, we are concerned that the Proposed Rule speaks inconsistently about BP and that it, ultimately, proposes, in the context of PBM transactions, a definition of BP that conflicts with the plain language of the statute and existing CMS guidance. We are deeply concerned about this aspect of the Proposed Rule.

Prior to the implementation of the DRA, the Act provided that manufacturers must include in their BP calculation, for a single source or innovator multiple source drug, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States except for those entities specifically excluded by statute.[41] The statute further specifies that BP includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates (other than rebates under section 1927 of the Act), which reduce the price paid.[42]

It has been the Agency's policy, consistent with these provisions and the national rebate agreement, that to reflect market transactions, manufacturers should adjust the BP for a rebate period if cumulative discounts or other arrangements to a customer subsequently adjust the prices actually realized.[43] Although the DRA introduced some changes in the statutory scheme pertaining to authorized generics, those changes do not affect the issue that we wish to address.

A handful of analysts have read the Proposed Rule to possibly suggest that a concession paid to a PBM, whether or not it is known that the PBM has passed on a portion of that concession to its customer, must be aggregated with any concession paid to the PBM's customer in calculating BP. We believe that the Proposed Rule is unclear on this point. If the manufacturer does not know that a PBM has passed the concession through to its customer, we do not believe that there is any legal basis for CMS to assert that any concession paid to a PBM must be aggregated with any concession paid to the customer of the PBM.

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[41] 42 U.S.C. § 1396r-8(c)(1)(C)(2007).

[42] *Id.*

[43] Medicaid Drug Rebate Program Release No. 14 (December 20, 1994).

In the absence of knowing that the concession is passed through, the aggregated concession does not constitute a price to any entity. In the absence of knowing that the concessions are passed through, there is not one single aggregated price made available to the customers of the PBM. Instead, there are two different prices made available to two different customers. The language of the statute simply does not permit the Agency to consider two different customers in determining BP. As CMS itself concedes in this Proposed Rule, BP is the lowest price in any quarter to "any [single] entity."[44]

There is an important practical issue here as well. We note that most, if not all, PBMs refuse to provide any information to manufacturers about what portion of the PBM concessions, *if any*, are passed through to the customers of the PBMs. This makes sense because the PBMs are concerned that the manufacturers and the PBM's customers will then simply engage in direct contracting and exclude the PBM.

Bayer strongly opposes CMS' "plan[s] to address future clarifications to best price through the issuance of program releases" because these do not even afford manufacturers the opportunity for notice and comment.[45] We are particularly disturbed due to the fundamental problem we believe we have identified in CMS' proposed treatment of BP and our conclusion that it is inconsistent with the statute. Given the substantive nature of any change to BP, in light of its direct effect on manufacturers' Medicaid rebate obligations, we strongly believe that any attempt to issue guidance here that does not involve notice and an opportunity for comment as required by the APA would be subject to challenge.

B. Manufacturer Coupons (Section 447.505(c)(12))

The Proposed Rule includes coupons redeemed by entities other than the consumer in the calculation of BP.[46] We appreciate that CMS is attempting to distinguish between situations where a coupon is provided for the benefit of a particular provider and not for the benefit of patients. But this proposal is impractical

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[44] *See* 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 447.505(a)).

[45] *Id.*

[46] *Id.* (proposed to be codified at 42 C.F.R. § 447.505(c)(12)).

and introduces a meaningless test that fails to achieve the intended purpose. Bayer strongly disagrees with CMS' proposal which ultimately involves a completely arbitrary distinction between entity-redeemed and consumer-redeemed coupons. To the extent that coupons are intended to benefit patients, and not a narrow group of providers, CMS should not discriminate in its treatment of coupons that are submitted by a provider on behalf of a patient for the sake of convenience.

Manufacturer coupons generally fall into three categories: mail-in rebate, co-payment assistance/dollars-off, and free good coupons. Direct mail-in rebate coupons are usually submitted by a consumer directly to the manufacturer (along with a proof of purchase) and the rebate amount is sent directly to the consumer. Under the Proposed Rule, this discount would not impact BP and AMP for the product.

Co-payment assistance or dollars-off coupons are presented at the time of sale at a retail pharmacy and the consumer receives their discount from the retail pharmacy. Then, the retail pharmacy submits the coupon directly to the manufacturer, which reimburses the retail pharmacy the coupon discount amount in addition to a fair market value processing fee.

Finally, a free goods coupon offers consumers a certain quantity of free product at no cost. The consumer presents this type of coupon at the time of sale at a retail pharmacy and the consumer receives their product free of cost. As with co-payment assistance coupons, the retail pharmacy submits the coupon directly to the manufacturer. The manufacturer may choose to send a replacement product along with a fair market value dispensing fee to the retail pharmacy or reimburse the retail pharmacy for the cost of the product along with the fair market value dispensing fee.

Under the Proposed Rule, these last two types of transactions would affect both AMP and BP. Bayer believes that it makes no sense, from a policy perspective, that transactions that are the same or very similar in substance would have fundamentally different effects for price reporting purposes based on the mechanics of redemption. This would create distinctions without meaningful differences.

It is possible to articulate a meaningful distinction that would capture those rare situations where a coupon or other similar program is designed to benefit a provider (such as a retail pharmacy or a managed care entity) and not the patient. The Agency might distinguish these transactions based on how narrowly the programs are made available. If, for example, a coupon is only offered to customers of a single retail pharmacy chain, it would be fair to conclude that the predominant intent may be to benefit that chain, rather than patients more generally.

We urge CMS to rethink its proposal for two additional reasons as a matter of policy. First, when dealing with elderly, infirm, or vulnerable populations, a requirement that patients only be able to receive this form of assistance, without an effect on price reporting, if they directly seek redemption from a manufacturer will inevitably preclude this form of assistance being provided to those populations. Those populations are particularly ill-equipped to undertake redemptions. They must have the assistance of a provider in the mechanics of redemption, or they simply will not be able to access the assistance. We do not believe that this result is in the interest of the Medicaid program or the affected patients.

Second, the OIG has repeatedly raised concerns about cash or cash equivalents being provided directly to patients. We do not believe that CMS should, through its price reporting guidance, provide a direction to industry which is not consistent with the relevant OIG guidance.

IV. Additional Issues Related to Defined Terms

The majority of our discussion above relates specifically to the definitions of AMP and BP. We also want to direct your attention to two areas where the Proposed Rule should be clarified – the definitions of "single source drug" and "physician administered drug."

A. Single Source Drug (Section 447.502)

We are quite concerned about the definition of "single source" and "multiple source" drugs in the Proposed Rule in part because on its face, the Proposed Rule fails to account for most

biologic products. CMS' proposed definition of the term "single source drug" fails to acknowledge biologics approved under section 351 of the Public Health Service Act ("PHSA").[47] We urge CMS to clarify the definition of "single source drug" to appropriately include biologics approved pursuant to the PHSA.

A "single source drug" would be defined as "a covered outpatient drug which is produced or distributed under an original NDA approved by the Food and Drug Administration ("FDA"), including a drug product marketed by any cross-licensed producers or distributors operating under the NDA."[48] This definition does not include biologics approved pursuant to a biologics license application ("BLA").

A regulatory anomaly complicates this proposed definition. Although the FDA approves some biological products under section 505 of the FFDCA, the majority of protein-based biologics are approved under section 351 of the PHSA. To provide one example, although they are biological products, the FDA approves hormones and insulin under the FFDCA, not the PHSA. For products approved pursuant to the PHSA, they are approved under BLAs, not NDAs. As a result, all products approved under the PHSA fall outside of the proposed definition.

Bayer urges CMS to change the proposed definition of a "single source drug" in the Final Rule to expressly include all biologicals. This may easily be achieved by amending the proposed definition at §447.502 as follows: "a covered outpatient drug that is produced or distributed under an original NDA or BLA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA or BLA." We hope that CMS will revise the proposed definition of "single source drug" to include products approved under a BLA.

B. Physician-Administered Drugs (Section 447.520)

The DRA added the requirement that States collect rebates on certain physician-administered drugs using Healthcare Common Procedure Coding System ("HCPCS") codes or national

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[47] 42 U.S.C. § 351 (2007).

[48] *See* 71 Fed. Reg. at 77,196 (proposed to be codified at 42 C.F.R. § 447.502).

drug code ("NDC") numbers.[49] Because an NDC number is required for States to bill manufacturers for rebates, until now, many states were unable to seek rebates and manufactures were unable to pay rebates on physician-administered drugs when the underlying products were not identified by the NDC number. Because States must now require the submission of utilization data for single source physician-administered drugs using HCPCS codes or NDC numbers, Bayer will begin reporting those as required.

V. Manufacturer Reporting Requirements (Section 447.510)

The Proposed Rule addresses a number of issues related to manufacturer reporting requirements. We include below a few comments on the following issues: reporting frequency, restatement of base date AMP, and smoothing methodologies.

A. Reporting Frequency (Section 447.510(d)(1))

We applaud the proposal to read the DRA as creating a new requirement that manufacturers report AMP monthly and BP and customary prompt pay discounts quarterly.[50] Bayer agrees that this interpretation of the DRA is correct. Monthly reporting of BP and customary prompt pay discounts would serve no purpose. It would be burdensome to implement. Moreover, it was not, in our view, intended by Congress.

We also agree with the proposal to make AMP publicly available quarterly.[51] Bayer does not support making AMP available on a monthly basis. We think that there is tremendous value in reviewing numbers on a cumulative basis and avoiding the variability that will inevitably be associated with monthly reports. Accordingly, we believe that this will help CMS and others to focus on the most accurate, predictable measure of AMP.

B. Restatement of Base Date AMP (Section 447.510(c))

Bayer also supports CMS' proposal to allow manufacturers to recalculate base date AMP in order for the limited

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[49] *Supra* note 2 at § 6002.

[50] *See* 71 Fed. Reg. at 77,185.

[51] *See id.* at 77,198 (proposed to be codified at 42 C.F.R. § 510(d)).

purpose of adjusting base date AMP to remove prompt pay discounts.[52] We believe that this will equitably account for the historical differences in manufacturer calculations and those that will now occur under the DRA-mandated methodology.

However, we do have some important technical concerns related to this issue. It may be difficult for manufacturers to determine the exact amount of the prompt pay discount offered to purchasers when the base date AMP was set. For example, we set our base date AMP on many products well over a decade ago. Since that time, we have implemented a new information system. As a result, it is difficult, if not impossible, for us to retrieve and manipulate the old data to recalculate base date AMP.

Due to this practical issue, Bayer proposes that CMS allow manufacturers to determine base date AMP using reasonable assumptions, so long as those assumptions are stated when the base date AMPs are submitted to CMS.

C. Smoothing Methodologies (Section 447.510(d)(2))

We strongly support the proposal allowing manufacturers to use reasonable smoothing methodologies to decrease the volatility of monthly AMPs.[53] We share CMS' hope that the use of smoothing will increase the possible utility of monthly AMPs. Consistent with ASP, we encourage CMS to adopt the use of 12-month rolling average estimates of all lagged discounts for both the monthly and quarterly AMP as a "safe harbor." Within this safe harbor approach, however, we encourage flexibility to account for different systems and approaches, consistent with CMS position on ASP.

As indicated in the Proposed Rule, manufacturers could use a variety of smoothing methodologies to achieve these goals. Some may find that they achieve the most accurate and stable AMPs by using the look-back period that rolls forward each month. Due to their rebating and discounting practices, however, other manufacturers may find that the most accurate and stable monthly AMPs are achieved where the same 12-month look-back period is

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[52] *See id.* at 77,185.

[53] *See id.* at 77,186.

used for each of the three months in any particular quarter, using the twelve months immediately proceeding the first month of the current quarter. Under this alternate approach, the look-back period would roll forward quarterly as each new quarter begins instead of monthly.

VI. Additional Issues for Consideration

For your consideration, we offer comments on three additional issues presented in the Proposed Rule—the survey of retail prices, future clarifications, and the collection of information requirements.

A. Survey of Retail Prices

In the Proposed Rule, CMS does not address the survey of retail prices and State performance rankings, as mandated by section 6001(e) of the DRA.[54] We respect the Agency's decision to defer this discussion to a later date. When CMS moves forward to implement the survey, we urge CMS to use a consistent definition of "retail pharmacy class of trade" for AMP calculation and survey purposes. We fear that taking a different approach would only detract from the usefulness of the survey and render it meaningless for comparative purposes. Furthermore, we encourage CMS to provide ample notice and opportunity for comment on this aspect of the DRA implementation.

B. Future Clarifications

In the Proposed Rule, CMS expresses the need to have the ability to clarify the definition of AMP and BP in an expedited manner in order to address the evolving marketplace for the sale of drugs.[55] While we appreciate the Agency's willingness to be responsive to issues as they arise, we must point out that clarifications in the form of program releases and website postings cannot replace formal rulemaking, as a legal matter. This portion of the Proposed Rule suggests that formal notice and comment will not occur when clarifications are made to the definition of AMP. This troubles us greatly and we cannot support such a proposal.

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[54] *Supra* note 2 at § 6001(e).
[55] *See* 71 Fed. Reg. at 77,181.

Before issuing a substantive rule, Section 553 of the APA requires an agency to comply with notice and comment procedures.[56] A substantive rule is one that would effect a change in existing law or policy and affect individual obligations.[57] We believe that guidance with respect to AMP, in essence, necessarily implicates this standard, significantly, the Federal Circuit recently found that an agency's failure to comply with notice and comment procedures was grounds to set aside an agency rule.[58] Importantly, the court held that a Department of Veterans Affairs' Dear Manufacturer letter comprised a substantive rule that was enacted without compliance with the procedures required by the APA.[59] It stands to reason that the VA's Dear Manufacturer letter is analogous to AMP and BP guidance and would require notice and comment as well.

C. Collection of Information Requirements

We see that the Agency estimates that the Proposed Rule will result in only 124 additional hours of manufacturer time.[60] Bayer believes that this estimate is grossly understated. Admittedly, we are not completely certain what the hourly annual burden to comply with the Proposed Rule might be. We are assured, however, that it will far exceed the 31 hours per quarter that CMS suggests, by several hundred hours.

VII. Conclusion

Bayer looks forward to continuing to work with you to improve the health of Medicaid beneficiaries. We thank you in advance for your time and consideration of the above comments on the Proposed Rule.

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[56] *Supra* note 3 at § 551.

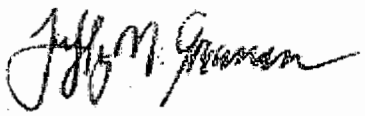
[57] *See supra* note 4; *see also* LeFevre v. Secretary of VA, 66 F.3d 1191, 1198 (Fed. Cir. 1995).

[58] *See* Coalition for Common Sense, 464 F.3d at 1318.

[59] *See id.* at 1308-09.

[60] *See* 71 Fed. Reg. at 77,189.

Sincerely,



Jeffrey M. Greenman
General Counsel and Secretary

Takeda

February 20, 2007

By Hand Delivery

FEB 20 2007

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

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

Takeda Pharmaceuticals North America, Inc. ("Takeda") submits these comments to the Centers for Medicare and Medicaid Services ("CMS") in response to the Proposed Rule implementing the provisions of the Deficit Reduction Act of 2005 ("DRA") pertaining to the Medicaid Drug Rebate Program.[1] We are most grateful for the opportunity to comment on CMS' Proposed Rule and we appreciate the substantial effort that CMS has taken in an effort to provide clear guidance on a host of Average Manufacturer Price and Best Price issues.

We would like to take this opportunity to offer a general comment regarding the application of the Proposed Rule, when finalized, and make specific suggestions on certain components of the "retail pharmacy class of trade" provisions. Takeda believes that it is important that CMS incorporate the revisions noted in this letter within its final regulations to ensure the regulation's operational success, its internal consistency, and its consistency with the Medicaid drug rebate statute (42 U.S.C. § 1396r-8, *as modified by* Pub. L. 109-171 (Feb. 8, 2006)). However, we do have significant concerns about some of the components of the Proposed Rule.

I. It Is Critically Important That the Final Rule is Applied Prospectively Only.

We note that a few analysts have interpreted the Proposed Rule as reflecting an intent to apply its terms retrospectively. Takeda strongly opposes any suggestion that the Final Rule may be applied retrospectively. CMS does not have express authority from Congress to promulgate a retroactive rule; therefore, it is barred from doing so. Furthermore, retrospective application of the Proposed Rule would be arbitrary and capricious because (i) the Proposed Rule seeks to reverse certain long-standing CMS policies; (ii) the Proposed Rule addresses issues that CMS has not previously addressed; and (iii) retrospective application of the Rule is not operationally feasible. Thus, as explained in further detail below, we believe CMS must ensure that the Final Rule is implemented only in a prospective manner and revise language in the

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

Proposed Rule that might be misread to suggest that manufacturers may need to revise their reported drug prices from quarters preceding the implementation of the Final Rule.

First, the case law evaluating the Administrative Procedures Act has required prospective only application of substantive changes in regulatory policy after notice and an opportunity for comment. *See, e.g., 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). Moreover, in *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988), the Supreme Court made clear that the U.S. Department of Health and Human Services cannot promulgate retrospective rules without express authority from Congress. Because the Medicaid drug rebate statute, as amended by the DRA, does not expressly authorize HHS or CMS to promulgate retrospective rulemaking related to BP and AMP, CMS is barred from doing so.[2] If CMS were to attempt to implement the Final Rule as having retrospective effect, implementation of the Final Rule will likely be delayed by manufacturer challenges under the *Coalition for Common Sense* and *Bowen* decisions.

Second, to apply the Final Rule retrospectively would mean that CMS has elected to turn its back on prior guidance that it has provided to the pharmaceutical manufacturer industry, and on which the industry, in turn, has relied upon and gone to great lengths to implement.[3]

Third, any attempt to retroactively apply the proposals contained in the Proposed Rule would only deepen our concerns about the absence of notice and the opportunity to comment in previous efforts by the agency to issue guidance affecting the Medicaid rebate program. Indeed, we continue to have grave due process concerns about the manner in which CMS has issued past directives with respect to the determination of AMP and BP through manufacturer releases and other sub-regulatory mechanisms which do not afford manufacturers appropriate notice and comment. Reversing prior directives on a retrospective basis would be all the more problematic; it would belie principles of fundamental fairness.

In addition, manufacturers, in good faith, have relied upon CMS' express directive contained in the Medicaid Rebate Agreement that they make reasonable assumptions when CMS has not provided specific guidance, such as the treatment of Part D sales and concessions for purposes of the AMP calculation. If the contents of the Proposed Rule were to be applied retrospectively in areas where the lack of any prior CMS guidance has forced manufacturers to make reasonable assumptions, the Final Rule would unfairly penalize manufacturers for their good-faith reliance on the reasonable assumptions doctrine and substantially undermine the ability and willingness of manufacturers to rely upon guidance given by CMS.

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[2] *Bowen*, 488 U.S. at 208 (emphasis added). As stated in *Bowen*, "Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language *requires* this result." *Id.*

[3] For example, CMS clearly reverses long-standing policy with respect to the treatment of sales to long-term care ("LTC") pharmacies without acknowledging that its proposed policy is a deep departure from prior written guidance in the Medicaid Drug Rebate Program Releases and without making clear that such reversals in policy will apply prospectively only.

Furthermore, retrospective application of the Proposed Rule would complicate recalculation filings that have been submitted by manufacturers to CMS prior to the issuance of the Proposed Rule and that are pending before CMS. Indeed, Takeda engaged in extensive and sustained discussions over a period of almost five years with CMS regarding a recalculation it filed with CMS in October 2006. We are concerned that we undertook great expense and exerted significant effort to recalculate our Medicaid prices in accordance with the regulatory regime in existence at the time of our recalculation filing. If CMS were to now give the Proposed Rule retrospective effect, it would require both manufacturers and CMS to overhaul pending recalculations. This would not be in either manufacturers' or CMS' interest.

Thankfully, CMS appears to have recognized the prospective nature of the DRA and the Proposed Rule. We conclude this because the Congressional Budget Office ("CBO") budgetary estimates associated with the DRA only discuss savings from the year 2006 forward and CMS' Regulatory Impact Analysis ("RIA") associated with the Proposed Rule only discuss savings from the year 2007 onward. If a retrospective application had been intended, Executive Order 12866 (amended by Executive Order 13258) would have required CMS to assess "both the costs and the benefits of the intended regulation".[4]

Because it appears that CMS is committed to prospective application of the Final Rule, we respectfully request that CMS make this point clear in the Final Rule.

II. Retail Pharmacy Class of Trade Issues

Takeda has significant misgivings with respect to CMS' proposed treatment of hospital outpatient pharmacy sales and manufacturer coupons. With respect to these categories, we are troubled by CMS' proposed treatment of these transactions, and urge CMS to revise its proposal consistent with our comments below.

In other instances, we agree with CMS' treatment of the class of trade, but request that CMS permit manufacturers, consistent with CMS' own prior guidance, to continue to make reasonable assumptions when data is incomplete or unavailable. Specifically, the Proposed Rule poses significant operational difficulty with respect to (i) the determination of retail versus non-retail sales in the non-mail order Pharmacy Benefit Manager ("PBM") sales category; and (ii) the restatement of baseline AMP to account for any customary prompt pay discounts. We believe that it will be operationally infeasible to provide CMS with precise data in these two areas; therefore, CMS should make clear that reasonable assumptions are permissible with respect to these aspects of the calculation.

Furthermore, we urge CMS to develop a comprehensive list of qualified SPAPs and confirm that only sales and concessions to qualified SPAPs which appear on CMS' then-current qualified SPAP list are to be taken into account for AMP purposes.

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[4] Given both that retroactive application would create a host of serious problems as described above and that the Proposed Rule contains only a prospective CBO budgetary estimate and prospective RIA, a Final Rule with retrospective application would, in our review, be void under the APA and Executive Order 12866 (as amended by Executive Order 13258).

We set forth our specific concerns below.

A. CMS Should Change its Positions With Respect to Certain Classes of Trade.

1. Hospital Outpatient Pharmacy Sales

CMS proposes to include hospital outpatient pharmacy sales in the AMP calculation. This proposal is operationally infeasible. In our experience, hospitals do not generally track drug utilization on an inpatient versus outpatient basis, and, therefore, will not be in a position to provide such information to manufacturers for purposes of the AMP calculation. For this reason, we urge CMS to exclude all hospital pharmacy sales from AMP because the vast majority of the sales are inpatient.

Drugs dispensed at a hospital, whether dispensed for inpatient or outpatient purposes, are generally dispensed from one, integrated hospital pharmacy. In order to track what portion of its pharmacy's sales are outpatient, hospitals will need to develop sophisticated utilization tracking software. Many hospitals, particularly rural and small, community-based hospitals, will not be able to afford such software. Therefore, we anticipate numerous instances in which hospitals will be unable to provide us with accurate hospital pharmacy outpatient utilization data.

Given that many hospitals are not in a position to provide hospital pharmacy outpatient utilization and given that we generally expect that most hospital pharmacy sales will be to its inpatient population, we respectfully request that CMS exclude outpatient hospital pharmacy sales from AMP.

2. Manufacturer Coupons

Takeda seeks a thoughtful reconsideration by CMS of its proposed treatment of manufacturer coupons. Takeda strongly believes that manufacturer coupons should be excluded from AMP and BP calculations where they are intended to provide a direct benefit to the patient, regardless of whether the consumer or a third party redeems the coupons. Indeed, it makes no sense to create disparate treatment of the same basic transaction based on who physically redeems the coupon. The critical question should instead be whether the patient receives the benefit of the coupon's savings or whether the coupon was designed to be a selective benefit to a pharmacy, managed care entity, or other provider. Basing the coupon exclusion on who physically redeems the coupon (e.g., the patient or a third party) seems arbitrary and inconsistent with CMS' efforts to establish logical and consistent policies with respect to the AMP and BP calculations. CMS should ignore the question of who redeems the coupon and look only to whether the benefit of the coupon is intended for the patient or for the selective benefit of a provider.[5]

[5] Coupons would constitute a selective benefit for providers, for instance, if patients could only acquire them from one pharmacy and the manufacturer intended that the pharmacy would market its business on that basis.

B. CMS Should Permit Manufacturers To Make Reasonable Assumptions When Operational Difficulties Limit Access to Data.

1. PBM Non-Mail Order Sales

We thank CMS for its recognition in the Proposed Rule regarding the difficulties manufacturers many encounter in obtaining data from PBMs. One area which CMS did not specifically address in the Proposed Rule are the difficulties associated with determining, and more specifically, obtaining documentation sufficient to prove, what portion of PBM non-mail order sales are attributable to the retail class of trade. We ask CMS to specifically acknowledge in the Final Rule that manufacturers must be afforded flexibility with respect to reasonably attributing PBM non-mail order sales to the retail and non-retail classes of trade. We believe such flexibility is critically necessary, given that the availability of data is often limited and manufacturers will, under the Proposed Rule, be required to certify their drug price reporting submissions.

Depending on a PBM's system capabilities and other issues, it may be operationally infeasible for a manufacturer to obtain precise retail versus non-retail data regarding a PBM's sales. While some PBMs may segregate their non-mail order sales data into retail and non-retail sales, and provide this data to manufacturers, other PBMs may not compile such data, or if they do, may not be willing to make this data available to drug manufacturers. While we expect the vast majority of non-mail order PBM sales to be distributed through retail pharmacies, due to the varying availability of data from PBMs, manufacturers may not be able to specifically document the point of distribution. Therefore, flexibility is critical in the determination of the PBM non-mail order sales.

Furthermore, in order to make CMS' proposal equitable, we cannot impress upon CMS strongly enough that it must not penalize a manufacturer for errors in its drug price reporting submission related to inaccurate data supplied by a PBM. When, for instance, a manufacturer has obtained reasonable assurances from the PBM that the data or representation is true and correct, the manufacturer should be permitted to reasonably rely upon those assurances.

We hope CMS will appropriately recognize in the Final Rule the operational challenges manufacturers will face in collecting data related to PBM non-mail order sales, and permit manufacturers to employ reasonable assumptions.

2. Customary Prompt Pay Discounts

The DRA requires that AMP be determined "without regard to customary prompt pay discounts extended to wholesalers," and that manufacturers report to CMS the customary prompt pay discounts extended to wholesalers.[6] The implementation of this provision requires that manufacturers restate their baseline AMP to account for any customary prompt pay discounts.

To the extent prior data on such discounts is available, it is our understanding that the term "customary prompt pay discount" is properly limited to only those discounts that were actually paid to a wholesaler for prompt payment of purchased drugs. Where prior data is not

[6] DRA § 6001(c).

available, we presume the term "customary prompt pay discount" means the discount that was typically offered by the manufacturer to the particular wholesaler for prompt payment *at the time of the filing of the price reporting submission related to such utilization*, as reasonably determined by the manufacturers. Any other reading of the requirement would be arbitrary, impractical to implement, and, we believe, inconsistent with Congressional intent. We respectfully request that CMS confirm this interpretation of this important term.

C. CMS Should Provide an Exclusive List of Qualified SPAPs

In Section 447.504(g)(12), CMS proposes to include within the AMP calculation sales and price concessions associated with state pharmaceutical assistance programs. We respectfully request that CMS confirm that this requirement is limited to only qualified SPAPs which appear on CMS' then-current qualified SPAP list, as posted on the CMS website, as of the date of the transaction.

Currently, manufacturers expend inordinate amounts of time and resources trying to determine whether SPAPs which do not appear on CMS' qualified SPAP list, but which otherwise may hold themselves out to be state pharmaceutical assistance programs, are truly qualified SPAPs as of the date of any particular transaction. Many SPAPs choose not to participate in the process necessary to be listed on CMS' qualified SPAP list. Other SPAPs move on and off the list as their program guidelines change, yet the CMS list does not provide historical dates of qualification and non-qualification. Manufacturers are in no position to determine whether any particular program is a qualified SPAP, and should be able to rely on the CMS list for price reporting certification purposes. For that reason, we further ask that CMS post on its website a complete and accurate list of qualified SPAPs that is updated on a frequent and regular basis.

III. Implementation Period

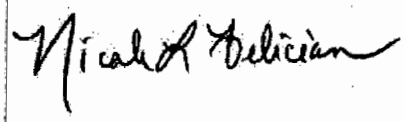
With the exception of the restatement of baseline AMP, CMS has not specified the time frame within which manufacturers will be required to comply with the Final Rule. As we hope CMS appreciates, manufacturers will need substantial time to revise and test their systems before they will be in a position to calculate AMPs and BPs in accordance with the requirements of the Final Rule. Indeed, most manufacturers will not be in a position to change their systems until the few key industry vendors for price reporting software make available software that has the required capabilities. We have been advised by our vendor that it will not even begin work on the new software until *after* the Final Rule is issued.

Because the vendors will need time to develop the new software and because manufacturers will need time to implement the software, test it, and train its relevant personnel on it, we strongly encourage CMS to provide manufacturers with at least a six-month period in which to conform their systems to the requirements of the Final Rule. To the extent that the six-month mark does not fall at the beginning of the first month of a quarter, we ask that CMS extend the implementation period to the beginning of the next full calendar quarter following the six-month period. We believe that anything less than a six-month period is unrealistic from an implementation perspective, and that manufacturers, no matter how diligently they work to address the requirements of the Final Rule, will be unable to meet an implementation schedule that is any shorter in duration.

IV. Conclusion

Takeda greatly appreciates CMS' thoughtful consideration of these suggested modifications to the calculation of AMP. We welcome the opportunity to further discuss any of these issues with CMS.

Respectfully submitted,



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BERLEX

February 20, 2007

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Centers for Medicare and Medicaid Services
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VIA HAND-DELIVERY

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

Dear Acting Administrator Norwalk:

Berlex, Inc. ("Berlex") submits the following comments in response to the proposed treatment of prescription drugs under the Medicaid Drug Rebate Program ("Proposed Rule").[1] Berlex is committed to addressing unmet medical needs through research and development in the areas of oncology, gastroenterology, women's health, diagnostics, and neurology. We also market diagnostic imaging agents, innovative treatments in the areas of female health care and oncology, as well as specialized therapeutics for life-threatening and disabling diseases of the central nervous system and cardiovascular system.

Berlex fully supports the Agency's attempts in the Proposed Rule to bring greater clarification to the calculation of both Average Manufacturer Price ("AMP") and Best Price ("BP"). We applaud CMS' desire to clearly address manufacturer price determination methods in a manner that results in consistent Medicaid rebate calculations and provides manufacturers, the States, and others with greater certainty with respect to price reporting and rebate issues.

We agree with several aspects of the Proposed Rule. We are, however, disappointed with a number of the components of the proposal. Despite our grave reservations about some important issues addressed by the Proposed Rule, we believe that, with some important changes, the Centers for Medicare and Medicaid Services ("CMS" or the "Agency") can issue a Final Rule that will fully realize the Agency's intent to produce clear and internally consistent guidance.

In summary, Berlex presents the following comments for consideration:

- We support a prospective application of the Final Rule following its publication and a reasonable period for implementation thereafter.
- Berlex generally supports CMS' proposed treatment of sales to pharmacy benefit managers ("PBMs"), health maintenance organizations/managed care organizations ("HMOs/MCOs"), and Medicare Part D.

[1] Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77,174 (proposed Dec. 22, 2006)(to be codified at 42 C.F.R. pt. 447).

- We oppose the policy reversal with regard to sales to long-term care ("LTC") pharmacies and encourage CMS to continue its long-standing policy of including these sales in the calculation of AMP.

- We also strongly disagree with the proposed treatment of Medicaid transactions.

- Berlex favors the proposed treatment of the prompt pay discount and returns.

- We are deeply troubled by CMS' possible articulation of a BP requirement that may be read to require the aggregation of PBM concessions with concessions paid to customers of the PBM, even when a manufacturer does not know that the PBM has passed its concessions on to that customer. This proposal, if, in fact, it were to be made by CMS, would be inconsistent with the statute.

- We believe that the proposal regarding coupons would require disparate treatment for transactions that are indistinguishable in their substance. We urge CMS to abandon its focus on redemption mechanics, as that focus will yield arbitrary results.

- Berlex urges CMS to add additional clarity to the proposed definitions of "single source drug" by accounting for biologicals.

- We also urge you to clarify the prospective nature of the proposed definition of "physician-administered drug."

- In terms of manufacturer reporting obligations, we offer comments regarding the definition of "adequate documentation," reporting frequency, smoothing methodologies, and the restatement of base date AMP.

- Unfortunately, we cannot support the proposal regarding bundling. In fact, the Proposed Rule lacks sufficient specificity to provide us notice or an opportunity for comment on the proposal that CMS is offering.

- Finally, we offer our thoughts on the survey of retail prices, future clarifications, and collection of information requirements.

Berlex asks CMS to carefully consider our thoughts on the important issues that we address. We thank CMS in advance for consideration of our comments on these issues, which are discussed at greater length below.

I. Foundational Issues

Later in our comments we address a variety of issues related specifically to AMP and BP calculations. Before we begin, however, we would like to highlight two fundamental issues that pervade the Proposed Rule and apply to all aspects of our comments—the nature of

the Final Rule's application and the reliance on the recommendations made by the Health and Human Services Office of the Inspector General's ("OIG").

A. Prospective Application

We understand that a few analysts are concerned that the Proposed Rule may be read as having a potentially retrospective impact, particularly with respect to its AMP and BP elements that the Deficit Reduction Act of 2005 ("DRA")[2] did not mandate. We do not believe that CMS contemplated such an application. Indeed, we believe that CMS could not lawfully apply this Rule retrospectively. We urge CMS to state plainly its intent that the Final Rule will only apply prospectively.

The Proposed Rule contains significant, substantive changes to existing practices and guidance regarding the calculation of AMP and BP. Undeniably, the Proposed Rule is replete with entirely new guidance where manufacturers had previously been permitted to make any reasonable assumption they wished.[3] We offer two examples where CMS clearly reverses a long-standing policy.

The proposed treatment of sales to LTC pharmacies and sales related to State pharmaceutical assistance programs ("SPAPs") underscores that the Proposed Rule cannot, consistent with the Administrative Procedures Act ("APA"),[4] be applied retrospectively. Both proposals depart from prior written guidance in the Medicaid Drug Rebate Program Releases.[5] In each case, CMS fails to make clear that proposed policies will only apply prospectively. To prevent any further confusion, we urge CMS to address the application issue directly.

It is a settled principle of regulatory construction that in order for a provision to have retrospective application, the requirement must be explicitly and unmistakably set forth. In this instance, it is simply not the case that CMS has made it clear that retrospective application is their intention. Moreover, even if CMS were to state such an intent, we believe that the APA would prohibit such an approach.[6]

Even where the Proposed Rule does not represent a reversal in prior, specific guidance about the treatment of a particular item, it often represents a substantive change in policy and the applicable guidance. The Agency has directed manufacturers to make and act in accordance with reasonable assumptions in a variety of areas. CMS expressly permits manufacturers to make reasonable assumptions in the Rebate Agreement.[7] Over the years, manufacturers have done just that. To apply the Proposed Rule retrospectively would unfairly

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[2] Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (codified as amended in scattered sections of 42 U.S.C.).

[3] We appreciate that the elements of the Proposed Rule mandated by the DRA, particularly the change in the treatment of prompt pay discounts, take effect as of the effective dates listed in the DRA.

[4] Administrative Procedures Act, 5 U.S.C. § 500 et. esq. (2007).

[5] Medicaid Drug Rebate Program Release No. 29 (June 2, 1997).

[6] Coalition for Common Sense in Gov't Procurement v. Sec'y of Department of Veterans Affairs, 464 F.3d 1306, 1308-09 (Fed. Cir. 2006) *citing* Paralyzed Veterans of America v. West, 138 F.3d 1434, 1436 (Fed. Cir. 1998).

[7] Center for Medicaid Services, Medicaid Drug Rebate Agreement § II(i), http://www.cms.hhs.gov/MedicaidDrugRebateProgram/14_NationalDrugRebateAgreement.asp.

penalize manufacturers' good faith efforts to comply with requirements of the Medicaid program (the "Program") and their reliance on the reasonable assumptions that they made pursuant to CMS' instructions to do so.

In addition to the policy and legal reasons for a prospective application of the Proposed Rule, there are a number of serious practical limitations which dictate that the Final Rule should not be applied retrospectively. Due to systems limitations, it would be difficult, and, in many cases, impossible, for manufacturers to recalculate AMPs or BPs for prior quarters under a new methodology. The AMP calculation, in particular, is operationally complex. It often requires the gathering of detailed data sets and the use of sophisticated information systems. Even where recalculation is feasible, it would likely place a significant administrative burden on manufacturers as proposed. We suspect, however, that, in many cases, recalculation may simply no longer be possible. In fact, manufacturers or their customers may not have the data needed to revise retrospectively their calculations based on the many changes in price reporting guidance contained in the Proposed Rule. The lack of data and other operational issues would impose a tremendous challenge to many manufacturers. These significant operational obstacles counsel in favor of prospective application.

Given that the APA compels prospective application and that retroactive application would create a host of serious problems as described above, we believe a Final Rule with retrospective application would be void under the APA due to its radical departure from and expansion of the requirements of the Proposed Rule. Accordingly, the Final Rule should clearly state that prospective nature of its application.

B. Reliance on OIG Guidance

We commend CMS for its work on the Proposed Rule. The treatment of prescription drugs under the Program presents complex issues. Since the Program's inception, CMS has developed significant expertise with regard to the products provided. The Agency is intimately aware of the industry's attempts to secure clarification on a broad array of issues.

In several places in the Proposed Rule, CMS discusses OIG recommendations. We appreciate that the Act requires the Secretary to consider the OIG's recommendations regarding prescription drugs under the Medicaid Program. Nevertheless, we caution CMS to weigh carefully the OIG's recommendations.

Unlike CMS, OIG is not steeped in the history of many of these issues. We fear, without the benefit of CMS' broad policy experience, that OIG recommendations could lead to the inconsistent treatment of important issues. We appreciate the OIG's comments on the Program. But those comments must be tempered by acknowledging the inherent limitations of policy analysis offered by an enforcement agency which is not entrusted with responsibility for managing the Program. We cannot overstate the importance of clear, understandable price reporting guidance that is practical and consistent. We fear that the OIG may, at times, overlook legitimate policy considerations because of its lack of any operational perspective. Where inconsistent policy recommendations arise, we urge CMS to favor its own, seasoned conclusions and issue clear guidance based on that experience.

II. Determination of AMP (Section 447.504)

We commend CMS for articulating the rationale behind its proposals, and we appreciate the description of a particular test, where applicable. For example, in its definition of "retail pharmacy class of trade," CMS seems to articulate an assessment based on whether or not sales are available to the general public.[8] We appreciate this effort to describe the history and development of the Agency's thinking. But we are concerned the test, as articulated, lacks sufficient clarity. Before we can fully appreciate the application of this test, we need a better understanding of how broadly the Agency defines the term. It is particularly unclear whether availability to the general public turns on the number of affected patients and purchases or on the means of delivery. We can conceive of circumstances where one but not both apply. In light of this ambiguity, our comments, when possible, attempt to address the basis for the Agency's proposal.

The Proposed Rule takes a significant step forward in standardizing AMP calculations. However, our comments below urge CMS to further refine its guidance in a significant way. First, we discuss issues relating to specific classes of trade or types of customers, which include: PBMs, LTC pharmacies, mail order pharmacies, HMOs, Medicaid, Medicare Part D, and direct patient sales. Second, we address issues that could impact a variety of customer types. Our comments here focus on administrative fees, prompt pay discounts, bundling, returned goods, and the meaning of "adequate documentation."

A. Issues Related to Specific Customer Types

The DRA directed the Secretary to clarify the requirements for, and the manner in which, AMP is determined in a formal regulation.[9] In the Proposed Rule, CMS defines 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."[10] The Proposed Rule defines "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."[11] CMS further defines this term in the preamble, stating 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."[12]

We offer the following comments specific to PBM, LTC pharmacy, mail order pharmacy, HMO, Medicaid, Medicare Part D, and direct patient sales.

1. PBM Sales (Section 447.504(g)(6))

In the Proposed Rule, CMS calls for the inclusion of discounts, rebates, and other price concessions to PBMs associated with the retail pharmacy class of trade in the calculation of AMP.[13] We thank CMS for its discussion in the preamble of the price reporting

[8] 71 Fed. Reg. at 77,178.
[9] *Supra* note 2 at § 6001(c)(3).
[10] 71 Fed. Reg. at 77,196 (proposed to be codified at 42 C.F.R. § 447.504(a)).
[11] *Id.* (proposed to be codified at 42 C.F.R. § 447.504(e)).
[12] *Id.* at 77,178.
[13] *Id.* at 77,196-97 (proposed to be codified at 42 C.F.R. § 447.504(g)(6)).

challenges associated with PBM sales.[14] Because manufacturers face operational challenges in collecting data related to non-mail order sales, we urge CMS to clarify in the Final Rule that it will permit manufacturers to make and rely upon appropriate reasonable assumptions regarding PBM sales.

We thank CMS for its general understanding of the substantial difficulties posed in obtaining and analyzing data from PBMs. But we believe that CMS does not fully appreciate the extent of the problem. Proposing that manufacturers must specifically link a PBM concession to a retail class of trade customer demonstrates CMS' lack of comprehensive understanding. Below we examine the difficulties associated with PBM data.

It is often impractical, if not impossible, for a manufacturer to obtain precise retail and non-retail analysis on a PBM's non-mail order sales. This, of course, varies to some extent on a PBM's system and data capabilities and what level of data sharing is required under their established contracts. Some PBMs may provide data that may allow some manufacturers to segregate their non-mail order sales data into retail and non-retail sales in some circumstances. In our experience, however, this is not always the case for all sales. Indeed, many PBMs are unwilling or unable to make this data available to manufacturers. Some simply do not compile such data. Due to the varying availability of data, the flexibility to make reasonable assumptions in the determination of the non-retail class of trade is critical. For AMP to have any meaning whatsoever, CMS must allow PBM price concessions to reduce AMP.

In the context of PBM sales, our price calculations are only as accurate as the data provided to us. Where data from the PBM is unavailable—or would be too costly to obtain or to analyze—manufacturers should be able to rely upon representations made by the PBM regarding its customer mix. Manufacturers should be able to use this information to make reasonable assumptions regarding which sales are retail and which sales are not. Similarly, if data from a PBM permits analysis for some proportion of sales, but not all sales, a reasonable assumption should be permitted to allow the rates of retail to total sales to be applied to those sales for which data is lacking.

With the advent of the certification requirement contemplated in the Proposed Rule, the need for specific guidance authorizing and permitting the use of reasonable assumptions is all too clear. In the context of calculations regarding PBM sales, CMS should not hold manufacturers accountable in the event of errors in the PBM data. When a manufacturer acts in good faith, particularly where the PBM has represented in writing to us that the data is true and correct to the best of its knowledge, it does not stand to reason that either the manufacturer or the PBM should be held accountable for any mistakes or errors in that data.

Manufacturers should also be able to make reasonable assumptions based on data from one PBM and apply it to another similarly-situated PBM. In this vein, we hope that CMS will recognize appropriately in the Final Rule the operational challenges manufacturers face in collecting data related to non-mail order sales and permit manufacturers to make appropriate reasonable assumptions and to rely upon those assumptions.

2. LTC Pharmacy Sales (Section 447.504(h)(6))

[14] *Id.* at 77,179.

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CMS proposes to exclude from AMP the prices of sales to nursing home LTC pharmacies.[15] According to the Proposed Rule, these sales fall outside the retail pharmacy class of trade.[16] This proposal is fundamentally inconsistent with the guidance issued by CMS to date, and we are deeply concerned by this proposed shift in policy. We respectfully ask that LTC pharmacy sales continue to be included in the AMP calculation.

Berlex appreciates that the argument in favor of their exclusion rests on the retail pharmacy industry's belief that LTC pharmacies, like mail order pharmacies, pay less for drugs than retail pharmacies.[17] We understand that the proposed definition is designed to address the retail pharmacy industry's contentions that an AMP used for reimbursement to retail pharmacies should only reflect prices of sales to those pharmacies which dispense drugs to the general public.[18] We disagree, however, with the rationale CMS articulates for excluding such sales. An end's driven analysis of this, or any other, class of trade issue will not yield an appropriate result.

Important Medicaid policy clearly dictates inclusion of LTC pharmacy transactions. To begin, many LTC residents are dual-eligibles. It seems inconsistent to propose excluding LTC sales while at the same time proposing to include sales to Medicare Part D. We are unclear as to how these customers differ under the general public test as articulated. Moreover, because for so many drugs LTC pharmacy transactions are a significant portion of their market, the exclusion of those transactions from AMP would yield inaccurate and misleading AMPs.

Second, the costs of changing the pre-existing policy that included LTC pharmacy transactions would require substantial systems, policies, procedures, and data link changes that would more than offset the perceived benefit in "simplifying" the AMP calculation. Manufacturers and others have entered into agreements in reliance on clear and unambiguous statements of the applicable price reporting rules. It is simply not fair to change the underlying rules after we have entered into contracts based on that guidance. The rule contemplated by Congress was designed to address unanswered and ambiguous reporting issues in order to create more confidence in the system, not to reverse policy on clearly established points and further undermine confidence in that system.

In sum, we oppose the exclusion of LTC prices from AMP. Berlex is not persuaded that a shift from current policy is warranted or sound. For AMP purposes, we encourage CMS to reverse its position on sales to LTC pharmacies in the Final Rule.

3. Mail Order Pharmacy Sales (Section 447.504(g)(9))

Berlex fully supports CMS' decision to maintain its existing policy to include sales and price concessions to mail order pharmacies in the AMP calculation.[19] We agree with CMS that mail order pharmacies "are simply another form of how drugs enter into the retail pharmacy

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[15] *See id.* at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(h)(6)).
[16] 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(h)(6)).
[17] *Id.* at 77,178.
[18] *Id.*
[19] *See id.* at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(g)(9)).

class of trade."[20] Health care delivery continues to evolve. No longer is the neighborhood pharmacy the only means for patients to obtain prescriptions. For a variety of reasons, patients may choose to utilize mail order pharmacies. But the retail nature of the sale to that patient is no different if the prescription is picked up at the pharmacy counter or if it is shipped to his or her mailbox. We appreciate CMS' recognition of this point.

4. HMO/MCO Sales (Section 447.504(h)(5))

We commend CMS for including MCOs in its definition of HMOs, which the statute specifically excludes in section 1927 of the Act.[21] Since the Program's inception, the managed care model has continued to mature. Though staff model HMOs were once the cornerstone of managed care, that is no longer the case. Over the years our health care delivery system has also come to embrace preferred provider organizations ("PPOs") and point of service ("POS") plans, as well. It is wise to recognize a broad array of managed care models that accurately reflect the care provided to beneficiaries and remain consistent with the spirit of the statute. Accordingly, we think the Agency is proposing the correct step by permitting manufacturers to include all managed care entities in its proposed definition of "provider."[22]

With this said, consistent with our arguments above in the PBM concessions section, Berlex urges CMS to recognize an exception to the exclusion of managed care sales where a manufacturer claims PBM concessions. Almost invariably, those concessions will be related to managed care transactions. It would not be logical to include a managed care concession but to exclude the underlying sale. Importantly, this kind of flexible treatment of managed care and PBM transactions would provide manufacturers with reasonable alternative approaches, depending on whether they have or do not have end-customer data from PBMs.

5. Medicaid Sales (Section 447.504(g)(12))

CMS proposes to include Medicaid prices in the calculation of AMP.[23] Berlex is concerned by this proposal because it would inappropriately separate rebates from the underlying sales. It would also introduce dissimilar treatment for AMP and BP purposes. As such, we respectfully request that CMS exclude Medicaid sales from the AMP calculation.

By including Medicaid prices in AMP, it appears that this proposal would disconnect rebates from their underlying sales. We fear that doing so would artificially skew AMP and would not reflect the price actually realized by the manufacturer. Because the statute prohibits manufacturers from including part of the rebate, it is only fair to exclude both the rebate and the underlying sale from AMP calculations.

Moreover, we believe that the proposal would create a real potential for inadvertent errors stemming from this incongruent treatment. Congress expressly exempted Medicaid sales from BP.[24] Doing so encourages manufacturers to provide the lowest possible

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[20] *Id.* at 77,178.
[21] *Id.* at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(h)(5)).
[22] *See* 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 447.505(b)).
[23] *See id.* (proposed to be codified at 42 C.F.R. § 447.504(g)(12)).
[24] 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I)(2007).

prices to government health care programs. Given the statutory exclusion of Medicaid sales from BP, it follows that CMS should exercise its discretion by excluding them from AMP as well. This change would achieve consistency in AMP and BP calculations, which has significant advantages. Symmetrical treatment of these transactions noticeably reduces the difficulty involved in these already complex calculations.

Berlex is concerned by this proposal because it would inappropriately separate rebates from the underlying sales. The proposed disparate treatment for AMP and BP purposes is particularly troubling. This proposal would seem to increase the administrative complexity without any real benefit. Accordingly, we urge CMS to exclude Medicaid sales from AMP.

6. Part D Sales (Section 447.504(g)(12))

We generally support the inclusion of Medicare Part D sales in the AMP calculation.[25] Berlex applauds CMS for articulating consistent proposals for Part D and PBM sales. Generally speaking, Part D sales overlap significantly with PBM sales. We are pleased that CMS recognizes the need for similar treatment.

That being said, Berlex shares the same concerns for Part D sales that we expressed above regarding the price reporting challenges associated with PBM sales. We hope that CMS will likewise appreciate the substantial difficulties posed in obtaining and analyzing data from Part D plans ("PDPs"), Medicare-Advantage PDPs ("MA-PDPs"), and qualified retiree prescription drug plans for covered Part D drugs. Here again our ability to obtain data will rely on the a plan's system and data capabilities and what level of data sharing is required under their established contracts. Due to the varying availability of data, the flexibility to make reasonable assumptions in this regard is critical.

While Berlex supports the proposal to include Part D sales in AMP, we hope that CMS will recognize appropriately in the Final Rule the operational challenges manufacturers face in collecting data. Based on those challenges, we urge CMS to allow manufacturers to make and rely upon appropriate reasonable assumptions when including Part D sales in AMP.

7. Direct Patient Sales (Section 447.504(g)(7))

CMS proposes to include direct sales to patients in the calculation of AMP.[26] The Agency finds that direct sales to patients "are usually for specialty drugs through a direct distribution arrangement, where the manufacturer retains ownership of the drug and pays either an administrative or service fee to a third party..."[27] Berlex strongly opposes the inclusion of direct sales to patients in the calculation of AMP.

CMS proposes to define AMP as "the average price received by the manufacturer . . . from wholesalers for drugs distributed to the retail pharmacy class of trade."[28] When a manufacturer makes a patient-specific direct shipment, there simply is not a retail class

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[25] *See* 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(g)(12)).
[26] *Id.* (proposed to be codified at 42 C.F.R. § 447.504(g)(7)).
[27] *Id.* at 77,180.
[28] 71 Fed. Reg. at 77,196 (proposed to be codified at 42 C.F.R. § 447.504(a)) (emphasis added).

of trade transaction. The only sale is a sale directly from a manufacturer to a specific patient. The drug is not offered to or intended for the general public.

Moreover, the statutory language will not support CMS' proposed construction, even with the broad definition of a wholesaler supplied by the Medicaid Rebate Agreement.[29] To the extent that a patient is considered a "wholesaler," the clear distinction contemplated by the statute between a "wholesaler," on the one hand, and the "retail class of trade," on the other, would be eroded. In any event, a sale earmarked to a particular patient and never intended to be offered to the general public is not to the retail pharmacy class of trade, even as CMS uses that term in this Proposed Rule.

These are transactions directly between a specific patient and a manufacturer. Because the means of delivery often varies, delivery may occur through a number of different intermediaries. For example, a manufacturer may ship directly from its manufacturing facility to a patient. Or, a manufacturer may send its product, on a patient specific basis, through a specialty pharmacy that does not take title to the drugs. These are just two examples of the variety of avenues a product might travel from a manufacturer directly to the patient. Nonetheless, in the case of a direct patient sale, it is always true that a product is marked for a specific patient and not available to any member of the general public.

For a variety of classes of products, particularly orphan drugs, there are important policy considerations that encourage manufacturers to engage in direct patient sales. Such sales are usually targeted to small populations. In these circumstances, products are intended for one person, and only one person. Because of the often small market for these therapies, it is important that CMS policy encourages manufacturers to continue to engage in practices where the product follows the patient. Doing otherwise would make it difficult for patients to reliably obtain access to life-saving therapies. We fear that the proposed inclusion of these sales in the calculation of AMP unfairly penalizes manufacturers who elect for a non-traditional delivery method in the interest of best meeting patient needs.

Significantly, CMS has provided several pieces of guidance that manufacturers should exclude various direct items to patients in the calculation of AMP and other price reporting metrics. Indeed, historically, the idea that coupons designed to benefit patients should not have an effect on price reporting has to be based on the notion that the patient and concessions offered to the patient are distinct from those offered to others. CMS has repeatedly discussed this concept in providing guidance to various program participants and repeats it to some extent in the Proposed Rule itself, for example, in the manufacturer coupon proposal. It is difficult to see how patients, and similarly, physicians that receive product earmarked for an individual patient, could be considered a sale to a "wholesaler" or sales to the retail pharmacy class of trade. CMS' proposed inclusion of direct patient sales in the calculation of AMP is not consistent with the statute or CMS' own previous guidance in this area. Accordingly, CMS must exclude direct patient sales.

B. Issues Impacting Various Customer Types

[29] *Supra* note 7 at § I(ee).

Some issues related to the definition of the retail pharmacy class of trade are not linked to any single customer type. We discuss a number of issues below which relate to a variety of our customers. Specifically, we address administrative fees, prompt pay discounts, bundling, returned goods, and the issue of "adequate documentation."

1. Administrative Fees and Service Fees (Section 447.504(h)(11))

CMS proposes to exclude bona fide service fees from AMP but include all other service fees.[30] Consistent with our comments regarding the 2007 Medicare Physician Fee Schedule Proposed Rule, we encourage CMS to rely upon the group purchasing organization ("GPO") safe harbor associated with the federal Anti-Kickback Statute ("AKS") as it defines which service fees qualify as bona fide.[31]

PBM administrative fees, by virtue of the OIG's Guidance to Pharmaceutical Manufacturers,[32] have been analyzed by applying the GPO safe harbor to the AKS. At least from that time, many manufacturers have used the AKS Safe Harbor to determine the appropriate treatment of administrative fees for price reporting purposes, whether paid to GPOs or to PBMs. Some manufacturers, for instance, treat an administrative fee of 3 percent of the purchase price as a bona fide service fee and administrative fees in excess of that amount, if any, as price concessions. There is strong benefit, both to the government and to manufacturers, of a consistent policy under both the AKS and the price reporting rules. We believe that CMS should formally adopt this position as a price reporting rule. Specifically, we urge CMS to adopt a definition of bona fide service fees in this context that is consistent with the AKS Safe Harbor. The Final Rule should state that an administrative fee meeting the requirements of the Safe Harbor does not act as a reduction in price for price reporting purposes.

In this regard, we note that CMS says that it is proposing to use the bona fide service fee test from the average sales price ("ASP") guidance here in an AMP and BP context. But in reality the Proposed Rule would actually create a disconnect between the ASP practice and AMP and BP practice. As CMS will recall, it stated in the 2007 Medicare Physician Fee Schedule Final Rule that at least until additional guidance is issued manufacturers need not take administrative fees paid to GPOs or PBMs as a reduction to ASP, without regard to whether the bona fide service fee test was met.[33] It is critically important that CMS ensure consistency between the ASP methodology and the AMP and BP methodologies to the fullest extent practicable. This will reduce the risk of inadvertent errors, increase transparency in the calculations, and reduce the huge systems, data, and calculation costs involved in implementing different, inconsistent approaches.

2. Customary Prompt Pay Discounts

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[30] *Id.* at 77,197 (proposed to be codified at 42 C.F.R. § 504(h)(11)).
[31] *See e.g.* 42 C.F.R. § 1001.952(j)(2)(2006).
[32] *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).
[33] *See* 71 Fed. Reg. 69,624, 69,669 (Dec. 1, 2006).

The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers.[34] It does not define the term "customary prompt pay discount." CMS proposes to define a customary prompt pay discount as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date."[35] We appreciate CMS' clarification and proposed definition of customary prompt pay discounts.

Berlex fully agrees with CMS' definition to include the prompt pay discount that is then prevailing at the time of any AMP calculation. There are, however, significant administrative burdens associated with the tracking of individual prompt pay discounts. In light of these burdens, we urge CMS to allow manufacturers to make reasonable assumptions regarding whether customers take a prompt pay discount when offered. As a practical matter, we urge CMS to give manufacturers the discretion to make a reasonable assumption regarding these discounts.

3. Bundled Items (Section 447.502)

Bundled price concessions are commonly described as arrangements in which a purchaser's price for one or more drugs is contingent upon the purchase of other drugs or items. CMS has struggled, not only in the context of AMP but also in the context of ASP, to provide clear guidance.[36] We applaud CMS for considering providing guidance on the proper method to apportion price concessions among drugs sold under bundling arrangements.[37] We believe this guidance could be most helpful in assisting manufacturers with this difficult price reporting issue.

We do not believe, however, that the Proposed Rule contains enough discussion of this issue to provide reasonable notice and an opportunity for comment. Berlex respectfully suggests that CMS provide some alternative mechanism or forum for manufacturers and other interested parties to have more substantial and more specific communication with the Agency on this important issue. The Proposed Rule simply does not provide enough detail to allow for us to provide meaningful comments. For any discussion to be helpful, the scenarios at issue must be clearly presented and the proposed treatment or alternative treatment must be specified.

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[34] *Supra* note 2 at § 6001 (c)(1).
[35] *See* 71 Fed. Reg. at 77,179.
[36] In the Proposed Rule for the 2007 Medicare Physician Fee Schedule, CMS acknowledges that it has not provided prior guidance in the ASP context regarding the proper method to apportion price concessions across drugs that are sold under bundling arrangements and further directs manufacturers to make reasonable assumptions in their calculations as a result. *See* Medicare Program; Revisions Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, 71 Fed. Reg. 48,982, 49,004 (August 22, 2006)("Thus far, we have not provided specific guidance in the ASP context on the issue of apportioning price concessions across drugs that are sold under bundling arrangements. In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Social Security Act, Federal regulations, and its customary business practices.").
[37] *See* 71 Fed. Reg. at 77,177.

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We are disappointed with the lack of meaningful detail in this proposal because it essentially mirrors the bundling proposal CMS articulated last year in the ASP context.[38] After declining to proceed with that rather unspecific proposal in the 2007 Medicare Physician Fee Schedule Final Rule, we were hopeful that the proposal here would be more precise and clear. We fear that this is not the case. For instance, we are confused by the suggestion in the Proposed Rule that a bundle may consist of the same drug.[39] We do not understand what the Agency is suggesting here or how this might alter price reporting.

With that said, as a general matter, any bundled relationship should have price reporting treatment that accurately reflects the value of the bundle to the products that are the subject of that bundle, and we support that policy. Given the proposal you have articulated, we cannot provide any additional comment at this time. We hope for an opportunity to remark on a more refined, more fully articulated proposal in the future.

4. Returned Goods (Section 447.504(h)(13))

CMS proposes to exclude goods returned in good faith from the calculation of AMP.[40] We understand that CMS proposes this exclusion based on the premise that manufacturers accept returned goods pursuant to established internal policies and not in a manner designed to manipulate the calculation of AMP.[41] Berlex supports CMS' conclusion in this regard, and we ask that CMS specify that acceptance of a return in accordance with a pre-established returns policy will constitute a good faith return.[42]

Berlex supports this proposal because of the administrative burdens associated with allocating the returned goods back to the reporting period in which they were sold. We also find it important for CMS to treat returned goods consistently. Because the Medicare Part B program excludes returned goods from the calculation of ASP, Berlex is pleased to see CMS' proposal to similarly exclude goods returned in good faith from the calculation of AMP.

We believe that CMS' treatment of the returns issue consistently under ASP and AMP and BP counsels for consistent treatment of other issues. We note elsewhere in this Proposed Rule various inconsistencies in CMS' current proposal for AMP and BP purposes and its previous guidance under the ASP methodology. As a general matter, we urge consistency in the various calculations as the best way to achieve accuracy and predictability.

5. Definition of "Adequate Documentation" (Section 447.504(g)(1))

In identifying the sales, rebates, discounts, and other price concessions that manufacturers should include in AMP, CMS includes all sales to wholesalers except for those sales that can be identified with "adequate documentation" as being subsequently sold to any

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[38] *See supra* note 33.
[39] *See* 71 Fed. Reg. at 77,177.
[40] *See* 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 447.504(h)(16)).
[41] *See id.* at 77,181.
[42] *Id.*

excluded entity.[43] We note, however, that CMS provides no further clarification in the preamble as to what it means by the term "adequate documentation."

In order for Berlex and other manufacturers to comply with this requirement, we hope that CMS will make clear in the Final Rule that manufacturers may rely on reasonable assumptions in determining what constitutes adequate documentation. This would be particularly helpful in light of the certification requirements now attached to manufacturer reporting. It would be fundamentally unfair to require manufacturers to certify to accuracy in price reporting when the accuracy of the prices reported may be subject to criticism at some later date based on the adequacy of the underlying supporting documentation. This is particularly concerning since the Agency provides no guidance as to what constitutes sufficient documentation.

Given the variety of the issues that must be addressed in price reporting and the fact that the nature of the documentation will vary by item, we do not believe that CMS is in a position to supply specific guidance on the quality and the quantity of the documentation required in all of these instances. Accordingly, we think that an explicit recognition of the ability to make reasonable assumptions is the fairest approach and one that is entirely consistent with other circumstances where CMS has not been able to provide specific guidance.

III. Determination of BP

The Proposed Rule clarifies the definition of BP to include the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application ("NDA") approved under section 505(c) of the Federal Food, Drug and Cosmetic Act ("FFDCA").[44] Pursuant to that definition, CMS proposes to make clear that BP is the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed.[45] Berlex thanks CMS for this additional guidance on the definition of BP. In our comments below, however, we feel compelled to address several important issues related to PBM concessions and manufacturer coupons.

A. PBM Concessions (Section 447.505(b)(2))

We appreciate CMS' attempt to clarify the BP calculation. But we have some concern that the Proposed Rule speaks inconsistently about BP and that it, ultimately, proposes, in the context of PBM transactions, a definition of BP that conflicts with the plain language of the statute and existing CMS guidance. We are deeply concerned about this component of the Proposed Rule.

Prior to the DRA, the Act provided that manufacturers must include in their BP calculation, for a single source or innovator multiple source drug, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States except for those entities specifically

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[43] 71 Fed. Reg. at 77,196 (proposed to be codified at 42 C.F.R. § 504(g)(1)).
[44] *Id.* at 77,197 (proposed to be codified at 42 C.F.R. § 447.505(a)).
[45] *See id.* at 77,197-98.

excluded by statute.[46] The statute further specifies that BP included cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates (other than rebates under section 1927 of the Act), which reduce the price paid.[47] Consistent with these provisions and the national rebate agreement, it has been CMS' policy that in order to reflect market transactions, the BP for a rebate period should be adjusted by the manufacturer if cumulative discounts or other arrangements to a customer subsequently adjust the prices actually realized.[48] Although the DRA introduced some changes in the statutory scheme as it relates to authorized generics, those changes do not affect the issue that we wish to address.

Although the Proposed Rule is unclear on this point, a few analysts have read it to possibly suggest that a concession paid to a PBM must be aggregated with any concession paid to the PBM's customer in calculating BP, whether or not it is known that the PBM has passed on a portion of that concession to its customer. This is the only place where such a suggestion might, conceivably, be made in the Proposed Rule. In the absence of the manufacturer knowing that a PBM has passed the concession through to its customer, we do not believe that there is any legal basis for CMS to assert that any concession paid to a PBM must be aggregated with any concession paid to the customer of the PBM.

In the absence of knowing that the concession is passed through, the aggregated concession does not constitute a price to any entity, other than the PBM. In the absence of knowing that the concessions are passed through, there is not one single aggregated price made available to the customers of the PBM. Instead, there are two different prices made available to two different customers. The statute simply does not allow CMS to consider two different customers in determining BP. As CMS itself concedes in this Proposed Rule, BP is the lowest price in any quarter to "any [single] entity."[49]

As a practical matter, we note that most, if not all, PBMs refuse to provide any information to manufacturers about what portion of the PBM concessions, *if any*, are passed through to the customers of the PBMs. This makes perfect sense, of course, as the PBMs are concerned that the manufacturers and the PBM's customers will then simply engage in direct contracting to the exclusion of the PBM.

In light of this fundamental problem in CMS' proposed treatment of BP and its inconsistency with the statute, we strongly oppose CMS' "plan[s] to address future clarifications to best price through the issuance of program releases" which do not even afford manufacturers the opportunity for notice and comment.[50] Given the substantive nature of any change to BP, in light of its direct effect on manufacturers' Medicaid rebate obligations, we strongly believe that any attempt to issue guidance here that does not involve notice and an opportunity for comment as required by the APA would be subject to challenge.

B. Manufacturer Coupons (Section 447.505(c)(12))

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[46] 42 U.S.C. § 1396r-8(c)(1)(C)(2007).
[47] *Id.*
[48] Medicaid Drug Rebate Program Release No. 14 (December 20, 1994).
[49] 71 Fed. Reg. at 77,197 (proposed to be codified at 42 C.F.R. § 447.505(a)).
[50] 71 Fed. Reg. at 77,182.

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CMS proposes to include in the calculation of BP coupons redeemed by entities other than the consumer.[51] Although we appreciate that CMS is attempting to distinguish between situations where a coupon is provided for the benefit of a particular provider and not for the benefit of patients, CMS' proposal is not practical and introduces a meaningless test that fails to achieve the intended purpose. Berlex strongly disagrees with CMS' proposal which ultimately involves a wholly arbitrary distinction between entity and consumer redeemed coupons. To the extent that coupons are intended to benefit patients and not a narrow group of providers, CMS should not discriminate in its treatment of coupons that, for convenience sake, are submitted by a provider on behalf of a patient.

Manufacturer coupons generally fall into three categories: mail-in rebate, co-payment assistance/dollars-off, and free good coupons. Direct mail-in rebate coupons are typically submitted by a consumer directly to the manufacturer (along with a proof of purchase) and the rebate amount is sent directly to the consumer. This discount would not impact BP and AMP for the product under the Proposed Rule.

Co-payment assistance or dollars-off coupons are presented at the time of sale at a retail pharmacy and the consumer receives their discount from the retail pharmacy. In turn, the retail pharmacy submits the coupon directly to the manufacturer, which reimburses the retail pharmacy the coupon discount amount in addition to a fair market value processing fee.

Lastly, a free goods coupon offers the consumer a certain quantity of free product at no cost. The consumer presents this type of coupon at the time of sale at a retail pharmacy and the consumer receives their product free of cost. As with co-payment assistance coupons, the retail pharmacy submits the coupon directly to the manufacturer. The manufacturer may choose to send a replacement product along with a fair market value dispensing fee to the retail pharmacy or reimburse the retail pharmacy for the cost of the product along with the fair market value dispensing fee. Under the Proposed Rule, these last two types of transactions would affect both AMP and BP.

It does not make any sense, from a policy perspective, that transactions that are the same or very similar in substance would have fundamentally different effects for price reporting purposes based on the mechanics of redemption. This would create distinctions without meaningful differences.

To provide a meaningful distinction which would capture those rare situations that a coupon or other similar program is designed and intended to be a benefit to a provider (such as a retail pharmacy or a managed care entity) and not the patient, CMS should distinguish these transactions based on how narrowly the programs are made available. If, for instance, a coupon is only offered to customers of a single retail pharmacy chain, it would be fair to conclude that the predominant intent may be to benefit that chain, rather than patients generally.

As a policy matter, we urge CMS to rethink its proposal for two additional reasons, as well. First, particularly when dealing with elderly, infirm, or vulnerable populations, a requirement that patients only be able to receive this form of assistance, without an effect on

[51] *Id.* at 77,197 (proposed to be codified at 42 C.F.R. § 447.505(c)(12)).

price reporting, if they directly seek redemption from a manufacturer will inevitably preclude this form of assistance being provided to those populations. Those populations simply are ill-equipped to undertake redemptions. They must have the assistance of a provider in the mechanics of redemption, or they simply will not be able to access the assistance. We do not believe that this result is in the interest of the Medicaid program or the affected patients.

Second, the OIG has repeatedly raised concerns about cash or cash equivalents being provided directly to patients. We do not believe that CMS should, through its price reporting guidance, provide a direction to industry which is not consistent with the relevant OIG guidance.

In sum, we strongly disagree with CMS' coupon proposal. It ultimately involves a wholly arbitrary distinction between entity-redeemed and consumer-redeemed coupons. To the extent that coupons are intended to benefit patients and not a narrow group of providers, we urge CMS not to discriminate in its treatment of coupons that are submitted by a provider on behalf of a patient in the interest of convenience.

IV. Additional Issues Related to Defined Terms

Much of our discussion above relates specifically to the definitions of AMP and BP. In addition, we want to direct your attention to two areas where the Proposed Rule should be clarified—the definitions of "single source drug" and "physician administered drug."

A. Single Source Drug (Section 447.502)

As a manufacturer of various biologic products, we are quite concerned about the definition of "single source" and "multiple source" drugs in the Proposed Rule. On its face, the Proposed Rule fails to account for most biological products. CMS' proposed definition of the term "single source drug" ignores biologics approved under section 351 of the Public Health Service Act ("PHSA").[52] We urge CMS to clarify the definition of "single source drug" to appropriately include biologicals approved pursuant to the PHSA.

According to the Proposed Rule, "single source drug" means "a covered outpatient drug which is produced or distributed under an original NDA approved by the Food and Drug Administration ("FDA"), including a drug product marketed by any cross-licensed producers or distributors operating under the NDA."[53] This definition does not include biologicals approved pursuant to a biologics license application ("BLA").

The proposed definition is complicated by a regulatory anomaly. The majority of protein-based biologics are approved under section 351 of the PHSA, but the FDA approves some biological products under section 505 of the FFDCA. For example, although they are biological products, the FDA approves hormones and insulin under the FFDCA, not the PHSA. For products approved under the PHSA, they are approved under BLAs, not NDAs. As a result, all products approved under the PHSA fall outside of the proposed definition.

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[52] 42 U.S.C. § 351 (2007).
[53] 71 Fed. Reg. at 77,196 (proposed to be codified at 42 C.F.R. § 447.502).

The proposed definition of a "single source drug" should be changed in the Final Rule to expressly include all biologicals. Specifically, we urge CMS to revise the proposed definition of "single source drug" to include products approved under a BLA. This may be easily be achieved by amending the proposed definition at §447.502 as follows: "a covered outpatient drug that is produced or distributed under an original NDA or BLA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA or BLA."

B. Physician-Administered Drugs (Section 447.520)

The DRA added the requirement that States collect rebates on certain physician-administered drugs using Healthcare Common Procedure Coding System ("HCPCS") codes or national drug code ("NDC") numbers.[54] Because an NDC number is required for States to bill manufacturers for rebates, until now, many states were unable to seek rebates and manufactures were unable to pay rebates on physician-administered drugs when the underlying products were not identified by the NDC number. Since States must now require the submission of utilization data for single source physician-administered drugs using HCPCS codes or NDC numbers, Berlex will begin reporting those as required.

This approach presents a problem, however, with regard to contrast agents. These products are typically used during hospital-based radiological procedures. To the extent that contrast agents are used in the hospital setting, however, we consider them to be excluded from the Program pursuant to the exemption for "organized health care settings."[55] Specifically, covered outpatient drugs dispensed by certain MCOs and certain hospitals that employ a formulary system are not "subject to the requirements" of the Medicaid rebate section of the statute.[56] We understand the plain meaning of these words to exclude contrast agents administered in the hospital setting from the Medicaid rebate.

V. Manufacturer Reporting Requirements (Section 447.510)

The Proposed Rule addresses a number of issues related to manufacturer reporting requirements. We include below a handful of comments regarding some of the issues discussed. Please accept our remarks regarding reporting frequency, smoothing methodologies, and restatement of base date AMP.

A. Reporting Frequency (Section 447.510(d)(1))

CMS proposes to read the DRA as creating a new requirement that manufacturers report AMP monthly and BP and customary prompt pay discounts quarterly.[57] Berlex agrees that this interpretation of the DRA is correct. We commend CMS for its careful reading of the statute. Monthly reporting of BP and customary prompt pay discounts would serve no purpose, would be burdensome to implement, and was not, in our view, intended by Congress. Again, thank you for your appreciation of the issue.

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[54] *Supra* note 2 at § 6002.
[55] *Supra* note 46 at § 1396r-8(j)(2).
[56] *Id.* at §§ 1396r-8(j)(1) and (2).
[57] *See* 71 Fed. Reg. at 77,185.

We also agree with the proposal to make AMP publicly available quarterly—not monthly.[58] Because we think that there is tremendous value in reviewing numbers on a cumulative basis and avoiding the variability that will inevitably be associated with monthly reports, we believe that this will help CMS and others to focus on the most accurate and stable measure of AMP.

B. Smoothing Methodologies (Section 447.510(d)(2))

We very much agree with the proposal allowing manufacturers to use reasonable smoothing methodologies in an effort to decrease the volatility of monthly AMPs.[59] Like CMS, Berlex hopes that the use of smoothing will increase the possible utility of monthly AMPs. We encourage CMS, consistent with ASP, to adopt, as a "safe harbor," the use of a 12-month rolling average estimates of all lagged discounts for both the monthly and quarterly AMP. Within this safe harbor approach, however, we encourage flexibility to account for different systems and approaches, consistent with CMS' position in connection with ASP.

As the Proposed Rule indicates, a variety of smoothing methodologies could be employed to achieve these goals. Some manufacturers may find that they achieve the most accurate and stable AMPs by using a the look-back period that rolls forward each month. Because of the nature of their rebating and discounting practices, other manufacturers may find that the most accurate and stable monthly AMPs are achieved where the same 12-month look-back period is used for each of the three months in any particular quarter, using the twelve months immediately proceeding the first month of the current quarter. Under this alternative approach, the look-back period would roll forward quarterly, instead of monthly, as each new quarter begins. A safe harbor would permit manufacturers to use either.

C. Restatement of Base Date AMP (Section 447.510(c))

Berlex applauds CMS' proposal to allow manufacturers to recalculate base date AMP in accordance with the definition of AMP.[60] We believe that this will equitably account for the divergence in manufacturer calculations historically and those that will now occur under the DRA-mandated methodology.

We do have some technical concerns related to this issue. It may be difficult for manufacturers to determine the exact amount of the prompt pay discount offered to purchasers at the time when the base date AMP was set. For example, we set our baseline on many products more than 15 years ago and have since implemented a new information system. As a result, it is difficult, if not impossible, for us to retrieve and manipulate the old data to recalculate base date AMP. Due to such difficulties, Berlex proposes that CMS allow manufacturers to determine baseline AMP using reasonable assumptions to adjust baseline AMPs, so long as those assumptions are stated when the baseline AMPs are submitted to CMS.

VI. Additional Issues for Consideration

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[58] *See id.* at 77,198 (proposed to be codified at 42 C.F.R. § 510(d)).
[59] *See id.* at 77,186.
[60] *See id.* at 77,185.

BERLEX

For your consideration, we offer comments on the following additional issues presented in the Proposed Rule: survey of retail prices, future clarifications, and the collection of information requirements.

A. Survey of Retail Prices

Section 6001(e) of the DRA amends section 1927 of the Act to provide for a survey of retail prices and State performance rankings. In the Proposed Rule, CMS does not address this issue. Berlex respects the Agency's decision to defer this discussion to a later date. When CMS does move forward to implement this DRA provision, we urge CMS to use a consistent definition of "retail pharmacy class of trade" for AMP calculation and survey purposes. Doing otherwise would only detract from the usefulness of the survey and render it meaningless for comparative purposes. We also urge CMS to provide ample notice to the public and a full opportunity for comment on this element of the DRA implementation.

B. Future Clarifications

CMS expresses in the Proposed Rule the need to have the ability to clarify the definition of AMP and BP in an expedited manner in order to address the evolving marketplace for the sale of drugs.[61] While Berlex appreciates the Agency's willingness to be responsive to issues as they arise, we must note that clarifications in the form of program releases and website postings cannot replace formal rulemaking, as a legal matter. Berlex is concerned by this portion of the Proposed Rule, as it suggests formal notice and comment will not occur when clarifications are made to the definition of AMP. We could not support such a proposal.

Section 553 of the APA requires an agency to comply with notice and comment procedures before issuing a substantive rule. [62] A substantive rule is one that would effect a change in existing law or policy and affect individual obligations.[63] We believe that guidance with respect to AMP, in essence, necessarily implicates this standard. Recently, the Federal Circuit found an agency's failure to comply with notice and comment procedures as grounds to set aside an agency rule.[64] The court held that a Department of Veterans Affairs' Dear Manufacturer letter comprised a substantive rule that was enacted without compliance with the procedures required by the APA.[65]

C. Collection of Information Requirements

According to your calculations, we see that CMS estimates that the Proposed Rule will result in just 124-hour additional hours of manufacturer time.[66] Unfortunately, we believe that this estimate is grossly understated. Although we are not completely certain what the hourly annual burden to comply with the Proposed Rule might be, we are assured that it will far exceed the 31 hours per quarter that CMS suggests, by a factor of at least 20.

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[61] *See id.* at 77,181.
[62] *Supra* note 4 at § 551.
[63] *See supra* note 6; *see also* LeFevre v. Secretary of VA, 66 F.3d 1191, 1198 (Fed. Cir. 1995).
[64] *See* Coalition for Common Sense, 464 F.3d at 1318.
[65] *See id.* at 1308-09.
[66] *See* 71 Fed. Reg. at 77,189.

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VII. Conclusion

Berlex thanks you again for your consideration of the above comments on the Proposed Rule. We look forward to continuing to work with you to improve the health of Medicaid beneficiaries and thank you in advance for your time.

Very truly yours,

BERLEX, INC.

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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.

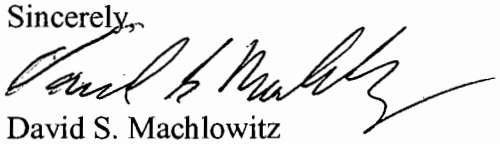
Summary and Conclusions

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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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.

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/LR

Karen Owen Gibbs

Enclosure (April 2005 Letter)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-15
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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.

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,

Dennis G. Smith
Director

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February 20, 2007

FEB 20 2007

By Hand Delivery

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."

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[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

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[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).

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,

Bill Sarraille

William A. Sarraille