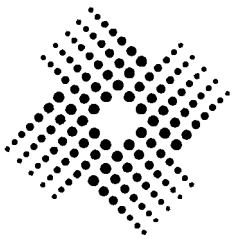

LTCPA

Long Term Care
Pharmacy Alliance

February 13, 2007

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-2238-P, Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

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

Dear Ms. Norwalk:

The Long Term Care Pharmacy Alliance (LTCPA) represents the leading providers of comprehensive pharmacy services for residents of long-term care (LTC) facilities. Our members provide pharmacy services to more than 60 percent of our nation's nursing home residents.

As you are aware, approximately 65 percent of America's nursing home residents are dually eligible for Medicaid and Medicare. Prior to 2006, dually-eligible residents received prescription drug coverage under state Medicaid programs. Implementation of the Medicare Modernization Act (MMA) resulted in reducing Medicaid coverage for prescription drugs for nursing home residents. As you are aware, there remain a significant number of nursing home residents for whom primary drug coverage resides with the Medicaid program. Included in this group would be disabled residents awaiting Medicare eligibility.

We are pleased to have this opportunity to comment on this proposed regulation. Our comments will follow the format of the proposed rule:

II. Provisions of the Proposed Regulations

§ 447.502 Definitions: Among the definitions proposed in the rule, LTCPA comments on the following:

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Phone: (202) 386-7559 Fax: (202) 386-7560www.ltcpa.org

Bona fide service fee: We agree that Average Manufacturer Price (AMP), for purposes of reporting, should not be reduced by fees paid by manufacturers to other entities for which services are received. Given the incentives for manufacturers to report a lower AMP for purposes of rebate assessment, we are concerned that the current definition may not be adequate. We anticipate that many of these services would be, or are currently performed by, drug wholesalers. Others could be performed by PBMs or health insurers.

We believe the rule should expressly include some of the obvious examples of these fees including payments to wholesalers for managing the chargeback systems and providing management reports. We understand that manufacturers also may pay fees to PBMs, Group Purchasing Organizations (GPOs) and others for administrative fees and various reports. Since these payments are not generally passed on to, or provide a benefit to, the retail purchaser of prescription drugs, we propose that these fees would be appropriate candidates for exclusion. These organizations (PBMs and GPOs) serve as market aggregators and provide opportunities to manufacturers to market their products to the retail marketplace. While manufacturer fees allow these organizations to operate profitably, they are not passed on to the retailer and result in lower acquisition costs.

Recommendation: We believe the standard for a bona fide service fee should explicitly include all fees paid by manufacturers to non-terminal retail providers.

Dispensing Fee: We agree that the dispensing fee should be defined as it is currently defined under the Medicare Part D program. Under CMS Part D regulations, *42 CFR 423.100,* CMS has made it clear that prescription drug plans (PDPs) need to determine dispensing fees based on an identifiable set of criteria. In the case of long-term care pharmacies, this would include the provision of services establish by CMS guidance on March 15, 2005 (Long-Term Care Guidelines).

The history of Medicaid reimbursement has been marked by targeted efforts by states to either reduce ingredient reimbursement or dispensing fees. Today, the typical state Medicaid dispensing fee is approximately $4.00. Yet the cost to dispense a prescription in long-term care pharmacy is estimated at over $11.00[1] (see dispensing fee study at http://www.ltcpa.org/pdf/BDO.pdf). As a result, states tend to rely on

[1] In 2000 dollars

reductions in either component without appropriate increases in the corresponding component. We believe it is appropriate to provide a detailed definition of this term and for CMS to mandate that states adopt existing federal law in applying this important concept in determination of the dispensing fee component of pharmacy reimbursement.

Current federal Medicaid regulations do not define what constitutes a "reasonable dispensing fee," and do not give any indication of how a state should set a "reasonable" dispensing fee. Pennsylvania Pharmaceutical Ass'n v. Casey, 800 F. Supp. 173, 176 (M.D. Pa. 1992). However, that term has been defined in case law, regulatory history, and other Federal regulations.

In Still's Pharmacy, Inc. v. Cuomo, 981 F.2d 632 (2d Cir. 1992), the Second Circuit found that New York's dispensing fees of $2.60 were unreasonable under §447.331(b). The court found persuasive "data indicating the New York pharmacists' 'burden rate' for dispensing a Medicaid prescription was approximately $3.39 in 1982, $4.65 in 1988 and $5.00 in 1990." Id. at 639. The court ruled for the plaintiffs based on "the failure of the State to respond to the increases...by fixing a reasonable dispensing fee as required by the Medicaid regulations." Id. Similarly in Ohio State Pharmaceutical Ass'n v. Casey, 587 F. Supp. 698 (S.D. Ohio 1984), plaintiffs claimed that the State dispensing fee was so low as to be unreasonable, arbitrary, and inconsistent with the Medicaid regulations. Although the court rejected Plaintiff's claim that the regulations called for the setting of a minimum dispensing fee, the judge agreed that the language "implicitly requires that the 'dispensing fee be reasonably related to the cost of doing business since its purpose is to allow participating providers a modest profit.'" Id. at 708 (quoting affidavit of HCFA employee serving as Medicaid representative to the State of Ohio). This case law review demonstrates that both the "burden rate" and "cost of doing business" are important factors in determining reasonableness.

Both cases were predicated upon an earlier version of the federal regulations that specifically defined how states were to determine dispensing fees. The regulatory history, however, indicates that although the specific methodologies to calculate a reasonable dispensing fee were deleted from federal regulation, the requirement that the fee still be "reasonable" was retained. More specifically, prior to 1987, State agencies were required to conduct periodic surveys to help determine appropriate dispensing fees, although agencies were not required to base dispensing fees specifically on the survey results. See 42 C.F.R. §447.333 (1986). The original regulatory scheme contemplated using the results of survey

data to help determine the reasonableness of dispensing fees. In 1987, HFCA deleted the requirement regarding dispensing due to "the interest of State flexibility and to avoid imposing unnecessary Federal procedural requirements as to how State agencies establish such fees." 52 Fed. Reg. 28,651 (1987). Although the survey requirement was eliminated for bureaucratic and cost reasons, the use of surveys to determine reasonableness is still consistent with the Medicaid regulatory scheme.

CMS should directly reference other HHS regulations to help define reasonableness. Specifically, Title 42, Part 50 of the C.F.R. discusses a similar (EAC plus dispensing fee) drug reimbursement structure (for federal health programs) in reference to Department of Health and Human Services Grants. In language virtually identical to the Medicaid rules, 42 C.F.R. § 50.504 states that one component in determining the maximum allowable costs of drugs is: "the acquisition cost of the drug plus a dispensing fee determined by the Secretary, in accordance with paragraph (b) of this section, to be reasonable." In turn, section 50.504(b) states:

(b) In determining whether a dispensing fee is reasonable, the Secretary will take into account:

(1) Cost components such as overhead, professional services, and profits,

(2) Payment practices of third-party payment organizations, including other Federal programs such as Title XVIII and XIX of the Social Security Act; and

(3) Any surveys by States, universities or others of costs of pharmacy operations and the fees charged in that particular area.

Given that the two regulations involve pharmacy reimbursement, and both use the identical "reasonable" dispensing fee language, they should be construed in pari materia by reading the definition of one into the other. The Medicaid regulation concerning dispensing fees should be read in pari materia. Statutes are in pari materia when they relate to the same matter or subject, even though they were enacted simultaneously and do not refer to each other expressly. See generally W. Eskridge Jr. & P. Frickey, Cases and Materials on Legislation 788 (1988). More specifically, the regulatory history strongly indicates that 42 C.F.R. §§ 50.504 and the regulatory language concerning "reasonable dispensing fees" should be read in pari materia.

On August 15, 1975, the Public Health Service (PHS), under the guise of the Department of Health, Education and Welfare (HEW) promulgated §50.504. This new regulation was designed to establish upper limits for the amount of PHS program funds that would be expended for the

purchase of any drug, and also set out the guidelines for setting a dispensing fee that still exist today. 40 Fed. Reg. 34514. On the same day in 1975, the Social and Rehabilitation Service (SRS), under the authority of the HEW, also promulgated regulations to "prescribe an upper limit on payments in the Medicaid (Title XIX) program for selected multiple-source drugs...and to require that payments for other drugs prescribed under title XIX be determined on the basis of acquisition cost as estimated by the State plus a dispensing fee, which ever is lower." 40 Fed. Reg. 34516. The Medicaid regulation discussing guidelines for setting a dispensing fee was at 42 C.F.R. §250.30. Section 250.30(b)(2)(i) stated that:

In establishing the dispensing fee, States should take into account the results of surveys of costs of pharmacy operation. States shall periodically conduct such surveys of pharmacy operational data, including such components as overhead, professional services, and profits.

Three years later, on September 29, 1978, the Health Care Financing Administration (HCFA), under the guise of HEW, reorganized and re-designated regulations for the Medicaid program. 43 Fed. Reg 45261. At that time section 447.333 regulated dispensing fess in the following manner:

(a) The agency may set the dispensing fee by taking into account the results of surveys of the costs of pharmacy operation. The agency must periodically survey pharmacy operations including-

(1) Operational data;
(2) Professional services data;
(3) Overhead data; and
(4) Profit data

Several years later, on July 31, 1987, HFCA deleted the requirement regarding dispensing due to "the interest of State flexibility and to avoid imposing unnecessary Federal procedural requirements as to how State agencies establish such fees." 52 Fed. Reg. 28651. The comments to the rule noted that "States will still be required to determine reasonable dispensing fees," (emphasis added) and HCFA expected that most States would "continue their present activities to establish a reasonable dispensing fee level and will document these and any new activities in their State plan." 52 Fed. Reg. 28651-52.

Although there is now no regulatory language defining what constitutes a "reasonable dispensing fee" under the Medicaid regulation §447.331, CMS at least should clarify that the term should be defined in reference to section 50.504. The regulations concerning dispensing fees were

promulgated on the same day, covered the same specific subject matter, and used much of the same language. For over ten years both statutes evaluated the reasonableness of dispensing fees in similar ways. Ultimately, when the dispensing fee language was deleted from the Medicaid regulations, the survey language was eliminated for bureaucratic and cost reasons and did not break with the regulatory scheme established in 1975. particularly in light of the changes that CMS proposes on generic drug reimbursement through the AMP regulation, such a clarification is needed.

The proposed clarification is particularly needed in the long term care pharmacy context, where industry surveys reflects that the average dispensing cost for long-term care pharmacies is $11.37 per prescription. As CMS has recognized in its Part D rulemaking, long term care pharmacies have elevated dispensing costs because they provide an entirely different set of services than retail pharmacies. These services include a specialized packaging system, frequent on-site delivery, maintenance of supplies for emergency use, and performance of drug utilization reviews. Thus, addressing dispensing fees is particularly appropriate in this rulemaking.

§ 447.504 Determination of Average Manufacturer Price
Definition of Retail Pharmacy Class of Trade: We agree with CMS' proposal to remove prices to nursing home pharmacies from the definition of retail class of trade for purposes of AMP calculation. We would go further and recommend that CMS should also extend this exclusion to mail-order drugs. As CMS has acknowledged in the proposed rule, mail-order has been shown to be more closely associated with chronic care drugs than with acute care medicines. For example, a standing prescription for medication to treat high blood pressure is a normal candidate for mail order, while a prescription for an antibiotic is generally not, since immediate administration is generally required.

In order to establish a standard that does not discriminate between chronic and acute medications, we believe it is important for CMS to exclude drugs distributed through mail order.

CMS also raises the issue of how PBM rebates, discounts, or other price concessions are to be treated in the calculation of AMP. CMS proposes that these discounts and rebates be included.

We believe this approach is inappropriate, in that price concessions to PBMs do not impact the acquisition cost of drugs to the terminal (retail)

distributor of drugs to the general public. Price concessions are intended to inure to the benefit of the PBM or its client and have no meaningful translation to prices paid by local pharmacies. For this reason, they should not be included.

We understand that AMP is not primarily intended to establish a baseline price for purposes of Medicaid reimbursement, but it is clear that this will likely be one of the outcomes. Manufacturer rebates and fees to PBMs do impact the net price charged by the manufacturer, which was originally the sole purpose of establishing this benchmark. However, since the DRA and CMS regulation proposes to encourage states to adopt it as a benchmark for reimbursement, we believe it is important for CMS to exclude these fees in the calculation of AMP.

Recommendation: CMS should exclude drugs dispensed through nursing home pharmacies and mail order pharmacies in its calculation of AMP. CMS should also exclude rebates and fees paid to PBMs in the calculation of AMP.

Customary Prompt Pay Discounts: The DRA prohibits the inclusion of prompt pay discounts in the definition of AMP. The proposed rule notes that the statute does not define this term and so attempts to define it in the proposed regulation. CMS has proposed to include prompt pay discounts "routinely" offered by the manufacturer to a wholesaler for prompt pay within a specified period of time.

CMS' proposed definition is overly restrictive for several reasons. First, manufacturers have a standard prompt pay policy (e.g., 2% if paid within 10 days, net 30). However, manufacturers occasionally extend prompt pay provisions upon product introduction or line extensions to encourage wholesalers and retailers to stock a product without a proven demand. Some manufacturers may, upon a product introduction provide payment terms that extend the prompt pay discount beyond the normal terms. In this case, CMS could argue that the prompt pay discount offered is not routine and therefore not excluded from AMP calculation.

Secondly, manufacturers establish prompt pay standards that are intended to apply to the retail marketplace and expect the wholesaler to honor this policy.

Recommendation: We propose that CMS delete the word "routinely" from its definition and include any prompt pay consideration the manufacturer passes on to the retail trade.

Treatment of Medicaid Sales: CMS proposes that prices paid by Medicaid programs should be included in the calculation of AMP. We agree with CMS' rationale for inclusion.

SPAP Price Concessions: CMS takes the inconsistent position that sales prices paid for prescriptions reimbursed under the SPAP programs be included in AMP calculation, but that rebates paid by manufacturers to these programs not be excluded. This is inconsistent with the CMS position on Medicaid rebates. The agency clarifies that Medicaid rebates are excluded from AMP calculation. If rebates are excluded from a state/federally funded program (Medicaid) they should also be excluded from a state-funded program.

Recommendation: CMS should exclude manufacturer rebates to SPAPs from AMP calculations as it does with Medicaid rebates.

Returned Goods: We agree with CMS' proposal that returned goods not be included in the calculation of AMP.

§ 447.506 Authorized Generic Drugs: We understand the rationale for CMS to classify authorized generic drugs as innovator multi-source drugs for purposes of rebate calculations. However, we are concerned about the unintended consequences that derive from this choice. If a manufacturer were to license a drug to a generic manufacturer in consideration of a royalty payment, but did not maintain control over pricing, sales or distribution of the product the licensee would be burdened by this requirement, unnecessarily injuring the licensee. In such instance the only possible pathway for a generic drug to come to market and achieve some level of competitiveness would be to require the filing of an Abbreviated New Drug Application (ANDA). While we are not certain whether this is a realistic assumption, we believe it may be an important consideration for this regulation.

Recommendation: CMS should treat authorized generic drugs as non-innovator multi-source drugs unless the manufacturer has licensed the product to another labeler and maintains no control over pricing, marketing or distribution.

§ 447.508 Exclusion from Best Price of Certain Sales at a Nominal Price: We understand that, under the provisions of the DRA, CMS has no discretion as to the choice of entities described in the proposed regulation. However, we caution that it may be possible for a distinct-part

skilled nursing facility (SNFs) within an eligible hospital to benefit from this exclusion. Most SNFs are not owned or operated by hospitals that are eligible for this exclusion, but those that do directly compete against these facilities. In the event a distinct-part unit is able to access prices that are excluded from best price, pharmacies that serve other facilities would be at a distinct competitive disadvantage.

Recommendation: CMS should clarify this section to assure that distinct-part units of hospitals eligible for this exclusion are not exempt from best price calculations for their purchases.

§ 447.514 Upper Limits for Multiple Source Drugs: The Federal Upper Limit (FUL) has traditionally been difficult for pharmacies, as its historically low reimbursement imposes penalties on pharmacies that attempt to substitute multisource drugs for branded products. Not withstanding the financial disincentives imposed by Medicaid reimbursement levels across the states, long-term care pharmacies have generally dispensed a higher percentage of multisource drugs than have other pharmacy sectors. As a result of both FUL and state maximum allowable cost (MAC) policies, we continue to see margins decrease for multisource drugs.

With respect to CMS' proposed regulations, we would encourage CMS to take measures to provide incentives to dispense lower cost generic drugs whenever possible. CMS can take concrete steps in this rule to ensure that the products identified as subject to FUL are:

- Broadly available in the marketplace, and;
- Available at prices that make dispensing these products under the FUL possible.

Our experience to date has been that these conditions are frequently not met when CMS announces new additions to the FUL list.

We believe CMS could best achieve these objectives by disseminating proposed additions to the FUL to the larger pharmacy community and allowing for comment by pharmacies as to product availability at a price that makes dispensing FUL products possible.

CMS also asks for comments on whether capturing 11-digit or 9-digit NDC data is preferable. We believe that 9-digit detail is adequate for this exercise, since per-unit pricing differences between package sizes is not generally significant.

Finally, we concur with CMS' proposal to ignore exceptionally low AMP prices in establishing the FUL, we agree this is a wise decision. As CMS points out, there are cases in which an AMP would be established during a promotional period that skews the pricing of the entity in such a manner as to make subsequent purchases exceptionally uneconomical. We urge CMS to keep this aspect of the proposed rule.

V. Regulatory Impact Analysis:

B.3: Effects on Retail Pharmacies: CMS makes no distinction in this section between traditional retail pharmacies and institutional pharmacies. CMS estimates the total impact of the provisions of this regulation on retail pharmacies to be $800 million in 2007. Further, CMS estimates that retail revenues would be affected by less than one percent as a result of these regulations. Finally, CMS suggests that the impact is mitigated by the retail pharmacies' reliance on non-drug sales to bolster its revenue.

As CMS is aware, the institutional pharmacy industry is composed of hundreds of small pharmacies in addition to the national companies. Institutional pharmacies do not engage in sales to the general public and do not rely on non-drug sales for revenue. Further, revenues of institutional pharmacies are disproportionately reliant on Medicaid, since long-term care facility residents are disproportionately represented in the Medicaid program. As such, we believe CMS has fundamentally misconstrued the regulatory impact, as well as the small business impact, of its proposed rule. We urge the agency to revise its estimate, and its proposed rule, to comply with the Small Business Regulatory Enforcement Fairness Act and other legal requirements.

FROM: Dr. Chad E. Wiggins
S & R Pharmacy
1606 S. Margaret
Kirbyville, TX 75956
409-423-2215

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade.—pg. 31-33

Inclusion in Best Price of PBM rebates, discounts and other price concessions— pg. 53

Treatment of Manufacturer coupons with regard to Best Price—pg. 55
Inclusion of Direct-to-Patient Sales with regard to AMP—pg. 41

AMP Must Differ From Best Price

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: *These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.*

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the market price of those drugs. *Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.*

For states to receive a rebate benefit more closely matching the marketplace, Best Price
was created as a ***contrasting measure*** to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. *In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.*

How PBM price concessions should be reported to CMS.—pg. 33

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper and grossly negligent. Specifically, *to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate.*

CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, *the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.*
PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, ***the PBM is allowed, again through lack of regulation; to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.***

**Allowing the use of 12-month rolling average estimates of all lagged discounts for
AMP.—pg. 70**

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are ***NOT*** accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that *the published pricing data will be at least 60 days behind the market place pricing.* Invoice pricing to community pharmacy, however, *continues to change* ***daily.*** In order to accurately realize market costs and reimburse retail pharmacy accordingly, *AMP data must be reported weekly.*

Use of the 11-digit NDC to calculate AMP —pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code. Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. *Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.* Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would **NOT** adequately cover pharmacy acquisition cost.

The 11-digit NDC must be used when calculating the FUL.

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.—pg. 110

CMS discusses impact on pharmacy:

** On independents: potential "significant impact on small, independent pharmacies."—

pg. 101

** On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011
("a small fraction of pharmacy revenues").—pg. 108

** "We are unable to estimate quantitatively effects on 'small' pharmacies, particularly
those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees. The impact on independent pharmacies also cannot be mitigated by an increase in state set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study. Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments. Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing. *All calculations must be independently verifiable with a substantial level of transparency to have accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.*

Final Comments:

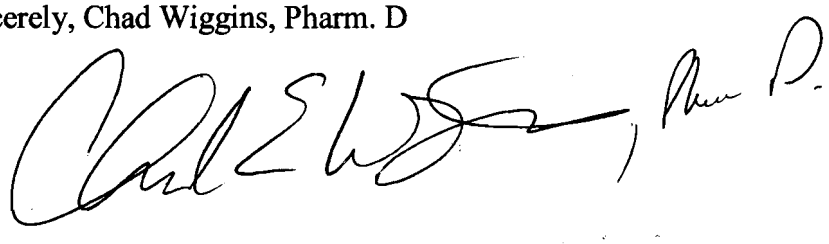
The rule, as currently written, would amount to gross negligence on the part of CMS if it ignores the GAO findings and input from all retail pharmacy organizations. By choosing to listen to the highly erroneous and self-serving input from PBM's, (which is readily apparent in the rule as submitted), CMS would be ignoring the one group (Independent Pharmacy) that truly makes the Medicaid plan work on the patient level. For example: Most independent pharmacies deliver, chains and discount pharmacies do not. That's better access! Many independent pharmacies are at the clinics near where patients live. That's more convenient!

Independent pharmacies were the most responsive and helpful entities for CMS in signing up patients for Medicare part "D" plans, only to find the reimbursements were pitifully low and payments from PBM's were slow in arriving.

As a new independent pharmacy owner I am quickly learning that CMS audits, reimbursement turnaround times, payments for generics, and support make Medicare part "D" claims an unhealthy part of my business. Medicare part D is low hanging fruit of my business.

And now the proposed definition of AMP will make another government plan more trouble than it is worth. In this case I have a choice! If the Final Rule on CMS-2238-P is not more accurately defined to reflect my true cost and include a reasonable fee for service I will not be taking Medicaid prescriptions after July 1st.

Sincerely, Chad Wiggins, Pharm. D



This is the website for making comments to CMS on AMP. If the link does not open from here you can copy http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=CMS and paste. It will take you to the appropriate starting page. You are looking for the last line that looks like this:

CMS-2238-P	Prescription Drugs	12/22/06	02/20/07	Go

Click on Go and fill in your background information.

Then it gets complicated!! Here is how I finally got it to work:

See the attachment for a picture of where I put my comments so they would all fit. I do not like how it seems to thro everything together so I am mailing mine as well. I have attached the "IPM comments on AMP" file that I mailed a well.

By regular mail. You may mail written comments (one original and two copies) to the following address ONLY:

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

Please allow sufficient time for mailed comments to be received before the close of the comment period.

By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2238-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-185

Last but not least, several pharmacies that do less than 10% Medicaid business are going to be adding this line to their comments:

"If the Final Rule on defining AMP is not changed my pharmacy will no longer accept Medicaid beginning on July 1st!"

Good luck with your comments. Please call me if you need to on how to send these comments (817-938-5700).

It is imperative that they receive as many comments as possible on the impact of their final rule.

Thanks, Joe Cain

75

Hugh M. O'NEILL
Vice President

February 20, 2007

VIA Electronic Mail Submission at www.cms.hhs.gov/eRulemaking

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

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

Dear Administrator Norwalk:

Sanofi-aventis appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the Medicaid Drug Rebate Program, published in the Federal Register on December 22, 2006 (the Proposed Rule). 1/ As a pharmaceutical company backed by world class research and development, we are developing innovative therapies to help Medicaid beneficiaries lead longer, healthier, and more productive lives. We are pursuing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines.

Sanofi-aventis is committed to the fight against disease throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products all over the world that constitute real therapeutic progress for patients. Our mission is to discover, develop,

1/ 71 Fed. Reg. 77,174 (Dec. 22, 2006).

and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs.

As a company dedicated to bringing advanced therapies to patients, our comments focus on our concerns about protecting patients' access to therapies and necessary services. These comments will address a number of issues of particular importance to sanofi-aventis. First, we ask CMS to refrain from finalizing the proposed new definition of bundled sale. We also would like CMS to clarify that patient coupons are not included in the calculations of Average Manufacturer Price (AMP) or Best Price, and provide additional guidance regarding the incorporation of authorized generic data in the AMP and Best Price calculations of branded products. For monthly and quarterly reporting of average manufacturer's price (AMP), we urge CMS to adopt the methodology used in the average sales price (ASP) context for smoothing lagged eligible price concessions. Finally, we also ask CMS to clarify a number of issues regarding the recalculation of the base date AMP figures, and to revise existing guidance to specify that manufacturers are liable for rebates in proportion to State Medicaid expenditures. Each of these issues is discussed in detail below.

I. CMS Should Provide Additional Guidance on the Proposed Definition of Bundled Sales.

CMS provided a new definition of bundled sale in the Proposed Rule. It defined a bundled sale as:

> An arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or, where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. [2/]

This definition differs significantly from the definition of bundled sales provided in the Medicaid rebate agreement. [3/] It also contains a number of vague and ambiguous terms. CMS has not provided any guidance in the Proposed Rule on how the agency interprets these terms or how the definition should be implemented.

Both the Biotechnology Industry Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA) are submitting comments to CMS in opposition to the finalization of the new bundled sale definition for these reasons. Sanofi-aventis is a member of both organizations and strongly endorses their written positions on this issue. Before CMS

2/ Id. at 77,195 (proposed 42 C.F.R. pt. 447.502).

3/ See 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991) (Medicaid Rebate Agreement at I(e)).

finalizes the definition of bundled sale, through a final rule or interim final rule with comment period, interested parties need additional notice regarding the scope and purpose of the revise definition and another opportunity to comment. Until that time, sanofi-aventis asks CMS to clarify that manufacturers may continue to rely on the definition of bundled sale in the Medicaid rebate agreement.

II. Patient Coupons Should Not Affect the Calculation of AMP or Best Price.

The Proposed Rule directs the inclusion of patient coupons in the calculations of AMP and Best Price where not redeemed by the consumer directly to the manufacturer. [4/] Sanofi-aventis opposes this proposal because we do not believe patient coupons have any impact on price for entities included in either the AMP or Best Price calculations. As for fully explained and discussed in the comments submitted by both BIO and PhRMA on this issue, patient coupons do not affect the price realized by entities included in the AMP and Best Price calculations, and any requirement to include such arrangements in those calculations could impact the continued viability of these important patient access programs. For the reasons articulated by those associations in their comments to the Proposed Rule, sanofi-aventis asks CMS to clarify that patient coupon transactions should not be included in the AMP or Best Price calculations.

III. CMS Should Clarify that Intercompany Transactions Are Not Part of an Authorized Generic's Sales and that the Primary Manufacturer Does Not Have To Use Transaction Level Sales Data for the Authorized Generic to Calculate the Blended AMP and Best Price.

An authorized generic is a drug that has its own national drug code (NDC), but which is marketed under the new drug application (NDA) of the innovator or brand manufacturer. [5/] The Deficit Reduction Act of 2005 (DRA) amended the Medicaid rebate statute to include authorized generics in the reporting requirements for the primary manufacturer's AMP and Best Price. [6/] CMS has included provisions in the Proposed Rule implementing this statutory provision. [7/] Sanofi-aventis urges CMS to provide additional guidance regarding this section of the Proposed Rule.

As explained in the preamble to the Proposed Rule, CMS interprets the DRA to "require the sales of authorized drugs that have been sold or licensed to another manufacturer" to be included by the primary manufacturer as part of the calculation of AMP and determination of Best Price for the brand drug. [8/] Sanofi-aventis believes that the "sales" referred to are those of the secondary manufacturer to its AMP- and Best Price-eligible purchasers. This term then is exclusive of any transfer or licensing payments the secondary manufacturer may make to the

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4/ 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. §§ 447.504(g)(11), .505(c)(12)).

5/ 71 Fed. Reg. at 77,183.

6/ Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6003.

7/ 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. § 447.506).

8/ Id. at 77,184.

primary manufacturer, which sanofi-aventis does not consider part of the authorized generic's sales. Excluding transfer and licensing payments from the sales figures of the authorized generic ensures that the blended AMP and Best Price of the branded product reflect the actual market prices for both the branded drug and authorized generic. It also avoids the administrative difficulty of appropriately accounting for transfer or licensing payments in the AMP and Best Price calculations. Sanofi-aventis therefore asks CMS to clarify that the blended AMP and Best Price of the branded drug are to be calculated without regard to any transfer or licensing payments made by the secondary manufacturer to the primary manufacturer or other intercompany transactions between the two manufacturers.

Although CMS stated in the Proposed Rule that the primary manufacturer must include direct and indirect sales of the authorized generic in its own product's AMP and Best Price, the agency did not provide guidance on the appropriate methodology for incorporating such data to derive the branded product's blended figures. Sanofi-aventis asks CMS to clarify that the primary manufacturer does not have to use the transaction level sales data of the authorized generic to determine the blended AMP and Best Price for the branded drug. Instead, the agency should clarify that the primary manufacturer may satisfy its obligation under the DRA and the Proposed Rule by using the AMP and Best Price as calculated by the secondary manufacturer or by using summarized transactional data provided by the secondary manufacturer that supports the AMP and Best Price calculated and reported to CMS for the authorized generic. Specifically, the manufacturer may derive the blended AMP for the branded drug by obtaining the AMP for the authorized generic along with its AMP-eligible units and calculating a weighted average AMP using the same information for the branded product, or by combining the products' AMP-eligible sales dollars (the figure in the AMP numerator) and dividing that figure by the products' combined AMP-eligible sales units (the figure in the AMP denominator). For Best Price, the manufacturer could obtain the Best Price for the authorized generic, compare it to the Best Price for the branded product, and report the lower of the two for the branded product.

Either of these approaches permits the primary manufacturer to use data that the secondary manufacturer already has calculated or summarized and so will decrease the operational burden associated with this requirement and facilitate the timely submission of blended data. Both approaches also ensure that the reported blended figures tie to the reported AMP and Best Price for authorized generic. Finally, these approaches will minimize the need for the two manufacturers to share commercially sensitive pricing information. For all of these reasons, sanofi-aventis urges CMS to clarify that the primary manufacturer may calculate the blended AMP and Best Price for the brand drug using the AMP and Best Price figures reported by the secondary manufacturer, or summarized transactional data that the secondary manufacturer used to derive the AMP and Best Price reported to CMS for the authorized generic.

IV. CMS Should Allow Manufacturers to Estimate Lagged Eligible Price Concessions for Monthly and Quarterly AMP Reporting Using the Methodology Adopted for Average Sales Price Reporting

The DRA now requires manufacturers to calculate AMP on a monthly basis, in addition to the continuing obligation to report AMP on a quarterly basis as well.[9/] The Proposed Rule directs that manufacturers are not to revise their monthly AMP figures beyond the submission deadline, and thus invited comments regarding the treatment of lagged price concessions for monthly reporting purposes and whether such an approach should be adopted for quarterly AMPs as well. [10/] In response to that request, sanofi-aventis urges CMS to adopt the ASP-smoothing methodology for AMP monthly reporting. Sanofi-aventis also asks CMS to allow manufacturers to use the same smoothing methodology for AMP quarterly reporting.

Many benefits recommend the use of the ASP smoothing methodology in the calculation of monthly AMP figures. The ASP-smoothing methodology has been subject to formal notice-and-comment rulemaking with input from interested parties. It already is in use by manufacturers of covered Medicare Part B drugs and therefore will be easier for both manufacturers and CMS to implement. Use of the ASP methodology in the context of monthly AMP reporting also is logical as both ASP and monthly AMP are used to calculate reimbursement rates.

These same considerations also recommend use of the ASP smoothing methodology in the calculation of quarterly AMP figures. Use of a smoothing methodology in the quarterly AMP calculation will eliminate the need to restate quarterly AMP submissions, resulting in significant administrative savings to manufacturers, States, and CMS because of the resulting decrease in prior period adjustment statements. [11/] In addition, such an approach would promote consistency in the calculation of monthly and quarterly AMP figures, which is particularly important when both sets of figures are to be public and used for reimbursement.

The ASP-smoothing methodology is based on a 12-month rolling average ratio of ASP-eligible lagged price concessions to ASP-eligible sales. [12/] To estimate eligible lagged price concessions for AMP reporting, manufacturers would calculate the ratio of AMP-eligible lagged price concessions to AMP-eligible sales for the most recent 12-month period and apply that ratio to the AMP-eligible sales for the month or quarter being reported. In the case of the monthly AMP, this ratio would be updated on a monthly rather than a quarterly basis. The quarterly AMP calculation would update this ratio on a quarterly basis as is currently the case with the quarterly ASP calculation.

For all of these reasons described above, CMS should adopt the ASP-smoothing methodology for estimating lagged eligible price concessions for monthly and quarterly AMP

9/ See id. at 77,185-86.

10/ Id. at 77,185.

11/ Best Price would still be subject to restatement and AMP would be restated only to correct errors.

12/ 42 C.F.R. § 414.04(a).

reporting. Sanofi-aventis also asks CMS to clarify that until CMS defines in regulation a methodology for estimating lagged ineligible sales in the ASP context, manufacturers may use in their AMP calculations the same methodology that they use for that purpose in the calculation of ASP.

V. CMS Should Clarify a Number of Issues With Regard to Recalculating Base Date AMP.

Sanofi-aventis supports CMS' decision to allow manufacturers to restate base date AMP to account for changes to the definition of AMP. [13]/ We note, however, that the decision to restate involves a number of competing interests. A manufacturer may decide that recalculating base date AMP is not worth the costs or effort if, for example, sales of a particular drug are minimal or the manufacturer does not believe that the changes to AMP will affect its additional rebates for a drug. CMS should therefore clarify that manufacturers have the complete discretion to decide whether or not to restate base date AMP for a particular product.

CMS should also clarify that customary prompt pay discounts are to be excluded when base date AMP is recalculated. The preamble to the Proposed Rule explained that CMS intended to allow manufacturers to restate base date AMP "[i]n order to reflect the changes to AMP as set forth in the DRA." [14]/ However, the actual text of the Proposed Rule states that "recalculation of the base date AMP must only reflect the revisions to AMP as provided for in [the definition of retail pharmacy class of trade]." [15]/ This provision ignores the change to AMP set forth in the DRA requiring the exclusion of customary prompt pay discounts. [16]/ CMS should clarify that such discounts should also be excluded when base date AMP is recalculated.

Pursuant to the DRA, manufacturers will remove customary prompt pay discounts from the AMP calculation beginning with the first quarter of 2007. [17]/ Manufacturers are not permitted to submit recalculated base date AMP figures, however, until the third quarter of 2007, at the earliest. As a result, additional rebate liability may increase due to changes in AMP between the first quarter of 2007 and the quarter in which recalculated base date AMPs are submitted and used to calculate additional rebates. Sanofi-aventis therefore asks CMS to clarify that the agency will revise manufacturer rebate liability for the quarters before recalculated base date AMP is submitted to the agency, beginning with the first quarter of 2007.

Even when the manufacturer has data available to permit recalculation, the process is likely to be technically difficult and impose significant administrative burdens. Sanofi-aventis asks CMS to allow manufacturers to recalculate base date AMP using the formula proposed by PhRMA in its comments to the Proposed Rule. The time and effort that can be saved from use of such a formula is obvious, and it provides an accurate means for determining the revised base

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13/ 71 Fed. Reg. at 77,185.

14/ Id.

15/ Id. at 77,198 (proposed 42 C.F.R. § 447.510(c)(2)).

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

17/ Id.

date AMP figure. These savings will enable manufacturers to submit the recalculations promptly, minimizing the number of quarters for which additional rebate liability will have to be revised. Sanofi-aventis therefore urges CMS to approve the use of PhRMA's proposed approach for recalculating base date AMP.

VI. CMS Should Revise its Prior Guidance and Clarify that Manufacturers Are Liable for Rebates in Proportion to State Medicaid Expenditures When Medicaid Is a Secondary Payor.

Through a series of Manufacturer Releases, CMS has articulated its position that manufacturers are liable to States for the full rebate amount when Medicaid pays any portion of a drug claim. [18]/ Sanofi-aventis disagrees with CMS' position on this issue and writes in support of the comments submitted by BIO and PhRMA asking CMS to revise its existing guidance for the reasons described in more detail below.

In a 2006 letter to former CMS Administrator Mark McClellan, Senator Charles Grassley, former chairman of the Senate Finance Committee, explained that "Federal law does not authorize States to collect rebates for the proportion of the payment made by the Medicare program." [19]/ Sanofi-aventis agrees with Senator Grassley's position on this issue. The Medicaid rebate statute requires manufacturers to pay rebates to reduce the amount expended by States under the Medicaid program. [20]/ Payment of a rebate that exceeds the State's expenditure for a drug is not a "reduction in the amount expended," but rather an overpayment that Congress did not provide for in the statute. The legislative history of the statute similarly indicates that manufacturer rebates were intended to ensure States realized the same discounted prices for drugs as other bulk purchasers, not windfalls, as is the case under CMS' current guidance. [21]/ As explained by Senator Grassley, the DRA amendment to the Medicaid rebate statute providing States with rebates "for which payment was made under this title" was intended to clarify this very point: that "the Medicaid rebate is only available for the Medicaid portion of the payment." [22]/

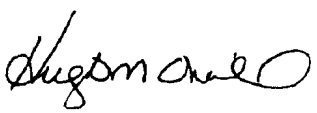
A revision to CMS guidance that would require the payment of rebates in proportion to Medicaid expenditures is consistent with the Medicaid rebate statute, the legislative history of that statute, the DRA amendments, and congressional intent, as clarified by Senator Grassley. Sanofi-aventis therefore asks CMS to revise its prior guidance on this issue in the Final Rule.

18/ See, e.g., Medicaid Drug Rebate Program Release #54 for Participating Drug Manufacturers (May 7, 2002).
19/ Letter from Senator Charles E. Grassley to the Honorable Mark B. McClellan (Aug. 14, 2006).
20/ 42 U.S.C. § 1396r-8(b)(1)(B).
21/ See 136 Cong. Rec. S12954-0 (1990), reprinted in 1990 U.S.C.A.N.N. 2017, 2108.
22/ Letter from Senator Charles E. Grassley to the Honorable Mark B. McClellan (Aug. 14, 2006).

VII. Conclusion

We thank you for your consideration of these comments on the Proposed Rule and hope we can continue to work with you to advance Medicaid beneficiaries' access to innovative and life-saving therapies. Please contact Mark Coin, Director, Federal Government Affairs, at 202 281 8524 if you have any questions on these comments. Thank you for your attention to these important issues.

Respectfully Submitted,



Hugh O'Neill
Vice President, Market Access and
Business Development

Because health matters

Mark Coin
Director, Federal Government Affairs

February 20, 2007

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

It appears that my attempt to post these comments electronically failed, as confirmed by this print out. I ask that you accept these comments if the comments were not received electronically. If the comments were received electronically, I apologize for the duplication and appreciate your consideration.

Respectfully submitted,

Mark Coin Mark Li

Director, Federal Government Affairs
202 281 8524

Enclosures

Docket Management Comment Form

Docket: CMS-2238-P - Prescription Drugs

Temporary Comment Number: 111950

Submitter:
Hugh O'Neill

Date: 02/20/07

Organization: sanofi-aventis

Category: Drug Industry

Issue Areas/Comments

General
please see the attached

Background
Background
pleasee see the attached

Response to Comments
Response to Comments

Attachments
No Attachments ??

Print | Comment on Another Docket | Exit

Print - Print the comment
Exit - Leave the application

MYLAN PHARMACEUTICALS INC.

February 20, 2007

ELECTRONIC COMMENTS
Centers for Medicare & Medicaid Services
Department of Health and Human Services

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

Dear Sir or Madam:

Mylan Pharmaceuticals Inc. ("Mylan") is pleased to have this opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") on the *Medicaid Program; Prescription Drugs Proposed Rule (the "Proposed Rule").*[1] Mylan is a leading manufacturer of prescription medicines specializing in developing and manufacturing generic pharmaceuticals. Mylan's customers include wholesalers, distributors, retail drugstore chains, and government agencies. Mylan manufactures and markets 160 generic products in nearly 400 product strengths, covering 46 therapeutic categories. As generics have become a more critical component of the health care system, consumers, insurers, and other prescription drug buyers have saved billions of dollars each year with the use of generics. These savings have resulted in critical savings to the Medicaid program and private drug benefit plans.

As a manufacturer of both generic and branded pharmaceuticals and a participant in the Medicaid Drug Rebate Program (the "Rebate Program"), Mylan strongly shares CMS' commitment to bring clarity and uniformity to the issues relating to Medicaid prescription drug pricing. The Proposed Rule, the issuance of which was mandated by the Deficit Reduction Act of 2005 (the "DRA"), was intended to "clarif[y] the requirements for, and manner in which, average manufacturer prices [AMPs] are determined..." as well as implement the DRA provisions relating to the various aspects of Medicaid prescription drug pricing.[2]

We appreciate the opportunity to comment on the Proposed Rule and look forward to working with CMS in bringing both clarity and operational feasibility to the Rebate Program. As a company, in general, we endorse the comments that have been submitted by the Generic Pharmaceutical Association ("GPhA"), of which we are a member. We are, however, taking this

[1] 71 Fed. Reg. 77174 (Dec. 22, 2006).
[2] Deficit Reduction Act ("DRA") § 6001(c).

opportunity to submit additional comments that are more specific to our concerns relating to the Proposed Rule. In particular, we have two primary concerns. First, it is important to recognize that AMP only reflects a snapshot in time that may not bear any relevance to market prices. In addition, as a complicating factor in the calculation of AMP and further limitation on the number's usefulness, manufacturers are often not privy to downstream (or indirect) sales and, thus, do not always have the data necessary to comply with CMS' proposed policies with respect to calculating AMP. Second, given the limitations inherent in AMP, manufacturer-specific AMP should not be made available to the "public," nor was that the intent of the DRA, which we discuss in detail below.

In addition to these fundamental considerations, however, which we have set forth in the beginning of our comments, we have organized our other concerns in their respective sections of the Proposed Rule.

I. Overall Concerns

A. AMP Is An Imprecise Number.

Our primary concern with respect to the Proposed Rule relates to the misconception that AMP is necessarily a price reflective of market prices. A myriad of business transactions cause periodic changes in AMP from month-to-month. Examples of such transactions include – backorders, temporary discontinuation of a product, low demand, and swings in sales and credits. As such, at any particular point in time, AMP may be different from the average price received by the manufacturer. Illustrative of this issue is the example below that demonstrates how the AMP of a single product could change as a result of transaction flow and timing:

- Manufacturer Sells to Wholesaler January 28 $100 / 100 units, January AMP = $1.00
- Wholesaler sells to eligible indirect customer on contract Feb 10 $80 / 100 units, February AMP after chargeback would be $.80
- Manufacturer pays Wholesaler a 10% rebate on purchases made during the quarter on March 31, March AMP after chargeback and rebate would be $.70

In this example, AMP is dependent on the timing of the original sale and downstream transactions that occur after the original sale, perhaps over multiple periods. This example also assumes that data is readily available during the relevant reporting period.

In addition, as mentioned above, while manufacturers have access to information concerning direct sales, they often do not have any information on indirect sales (unless there is a chargeback or some other mechanism to track the sale). Although intending to clarify the determination of AMP, instead, CMS proposes to include in, and exclude from, AMP calculations data that are not readily available, if at all, to manufacturers. As an example, CMS proposes to include Medicare Part D rebates[3] in the calculation of AMP provided that such

[3] Our comments with respect to Part D sales are discussed in detail in the "Determination of AMP – Section 477.504" section of this comment letter.

rebates are applicable to product sold to an eligible Medicare Part D beneficiary. However, manufacturers are rarely aware of whether their products are ultimately sold to an eligible Medicare Part D beneficiary, making this policy operationally infeasible. Consequently, although some of these Medicare Part D rebates will be correctly included as proposed, most Medicare Part D rebates will be inadvertently excluded by manufacturers. Either way, the resulting AMPs submitted to CMS will be inconsistent, at best, across manufacturers.

As such, CMS will need to be exceedingly clear in the guidance that it provides to manufacturers in calculating AMP to ensure that manufacturers are able to determine the sales and associated price concessions that should and should not be included in AMP and to ensure consistency in AMP calculations across all manufacturers.

B. The Publication Of Manufacturer-Specific AMPs To All Purchasers, Payers, And Consumers Is Unintended Under The DRA.

The DRA sets forth that –

> Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States ... the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website....[4]

In a subsequent provision, the DRA sets forth that the Secretary is to disclose "(through a website accessible to the public) average manufacturer prices."[5] Based on these provisions it is clear that Congress intended that AMP data be made available to States and the "public." However, there is no basis to believe that Congress intended to make manufacturer-specific AMP information available on a website accessible to the "public."

We believe that Congress' intent to make AMPs publicly available was to improve the transparency of drug pricing under the Rebate Program for the benefit of payers, which would be accomplished by permitting only States and their Medicaid programs to access manufacturer-specific AMP information on the CMS website. Accordingly, by providing manufacturer-specific AMP data on the agency's public website in a manner that allows only State Medicaid programs (or other authorized users) access, CMS would be in compliance with Congress' directive, as well as with the intent of the statute.

In addition, as addressed by GPhA in its comments, publishing manufacturer-specific AMP information to the public is fraught with significant concerns, including, reduced competition, anticompetitive concerns, and confusion among purchasers and payers. For these reasons, we ask CMS to take a reasonable interpretation of the statute and publish only the aggregated industry-wide weighted average AMPs for multiple source drugs. Publishing

[4] DRA § 6001(b)(1)(B).
[5] DRA § 6001(b)(2)(C).

manufacturer-specific AMP information would negate other applicable confidentiality provisions that the DRA did not change. A statute should not be accorded a meaning that eliminates the effect of certain of its provisions.

We also believe that these disclosure provisions must be implemented through notice and comment rulemaking, and the failure to do so violates the Administrative Procedure Act ("APA").[6] The APA requires agencies to give interested parties the right to participate in rulemaking through publication of a proposed rule, which includes "the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[7] As explained above, as well as in the comments from GPhA, there are many different possible means by which this provision can be implemented. As such, regulated businesses have a statutory right to notice as to how the information will be presented and to comment on the legal and policy implications of such decisions.

II. Comments to Specific Sections of the Proposed Rule

As mentioned above, AMP is not necessarily reflective of market prices. There are two key drivers of this number: (1) customer classification (e.g., eligible versus ineligible class of trade); and (2) transaction treatment (e.g., inclusion and timing). It is vital that these two components of AMP be applied in a uniform manner to ensure that the AMPs for the same products can be compared consistently across manufacturers. To this end, it is critical that CMS clearly define certain significant terms that are contemplated in the Proposed Rule. The remainder of our comments will address our concerns in the order that is set forth by CMS.

A. Determination of AMP – Section 447.504

1. Bundled Sales

CMS proposes that AMP calculations should be adjusted for bundled sales "by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations."[8] That is, the aggregate discount would be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. In the case of multiple discounted products in a bundle, the aggregate value of all the discounts should be proportionately allocated across all of the drugs in the bundle. The Medicaid Drug Rebate Operational Training Guide (the "Guide") defines the term "bundled sales" as "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."

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[6] 5 U.S.C. Chap. 5.
[7] 5 U.S.C. § 553.
[8] 71 Fed. Reg. at 77177.

As proposed, CMS seems to broaden the definition of the term "bundled sales" to potentially include routine multiple drug sales to entities such as wholesalers and group purchasing organizations ("GPOs"). We do not believe that the intent of the Proposed Rule was to require that manufacturers allocate on an item-by-item basis the original price of the drug product had it been sold separately. Accordingly, we recommend that CMS should not broaden the definition of the term "bundled sales."

2. Retail Pharmacy Class of Trade – Nursing Home Pharmacy

In the Proposed Rule, recognizing the concerns that have been raised relating to the inconsistencies in the way manufacturers determine AMP, CMS proposes to clarify such determination by revisiting the definition of "retail pharmacy class of trade." CMS proposes to define the retail pharmacy class of trade as "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."[9] Given this definition, CMS proposes to exclude prices to long-term care ("LTC") (or nursing home) pharmacies because LTC pharmacies do not dispense to the general public.

We are concerned that CMS has not clearly identified those entities that would be considered LTC (or nursing home) pharmacies.[10] Mylan encourages CMS to clearly define the attributes of entities that qualify as LTC pharmacies to avoid disparate treatment among manufacturers as they exclude prices to LTC pharmacies in calculating AMP. If manufacturers were to use different criteria for determining whether an entity is a LTC pharmacy, manufacturers' AMPs would not uniformly reflect the exclusion that CMS intended in the Proposed Rule. As such, CMS should clearly define the term "LTC pharmacy."

In addition, we recommend that CMS establish a list of those LTC pharmacies that should be excluded from the calculation of AMP in a "List of Excluded Class of Trade Entities," similar to the type of document attempted by the Office of Pharmacy Affairs's ("OPA's") list of eligible 340B entities.[11] This list would specify for manufacturers those entities that should be excluded when calculating AMP. As a result, CMS would ensure that manufacturers consistently categorize customers included in and excluded from AMP calculations as there are several types of entities that could (or could not) qualify as LTC pharmacies, depending on the interpretation. For instance, it is not clear whether the following would be considered a LTC pharmacy under the Proposed Rule – LTC pharmacies owned by a hospital, infusion centers, and rehabilitation centers.

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[9] 71 Fed. Reg. at 77178.

[10] According to MedPAC, there are approximately 15,000 skilled nursing facilities. See MedPAC Report to the Congress: Medicare Payment Policy (March 2006). In addition, according to the Long Term Care Pharmacy Alliance ("LTCPA"), there are five major national LTC pharmacies – Kindred Pharmacy Services, Omnicare, NCS Healthcare, NeighborCare, and PharMerica. These LTC pharmacies serve more than 1.5 million people including more than two-thirds of all nursing facility residents. See LTCPA website available at http://www.ltcpa.org/mission/pharmacy/default.asp.

[11] For the reasons addressed in this section, we recommend that CMS establish a similar list for all entities that should be excluded from AMP calculations as guidance to manufacturers.

Further, as we have mentioned, it is often operationally infeasible for manufacturers to identify those sales that are made to a particular type of entity (e.g., a LTC pharmacy), as opposed to another type of entity that might not satisfy the definition of a LTC pharmacy. Manufacturer sales data are captured at the contract level, but any included or excluded class of trade customer could purchase products from any wholesaler source contract. Thus, manufacturers have no way of determining whether final sales are made to excluded customers. Given this inherent difficulty with calculating AMP, it is imperative that CMS provide mechanisms by which manufacturers can calculate AMP as consistently as possible.

3. Pharmacy Benefit Manufacturers ("PBM") Price Concessions

CMS addresses in the Preamble to the Proposed Rule the difficulties involved in the treatment of PBMs for purposes of determining AMP. Both the U.S. Government Accountability Office ("GAO") and the Office of the Inspector General ("OIG") have recognized that the Rebate Program does not clearly address certain financial concessions negotiated by PBMs, and have recommended that CMS clarify the treatment of PBM rebates.[12] According to the OIG, manufacturers treat rebates and fees paid to PBMs in one of three ways – (1) not subtracting rebates or fees paid to PBMs from the AMP calculation; (2) subtracting the rebates or fees paid to PBMs; or (3) subtracting a portion of the PBMs rebates or fees from the AMP calculation.[13]

Based on these inconsistencies, CMS considered both the inclusion and exclusion of all rebates, discounts, and other price concessions to PBMs in the determination of AMP. Although CMS acknowledges the difficulty manufacturers face in determining the apportionment of PBM price concessions to the PBM, the insurer, and, if any, to the pharmacy, CMS states that excluding all PBM price concessions could result in an artificial inflation of AMP. As such, CMS proposes to include all rebates, discounts, or other price concessions provided by the manufacturer to the PBM that affect the net price recognized by the manufacturer for drugs provided to the retail pharmacy class of trade.

For several of the reasons addressed by CMS in the Proposed Rule, Mylan agrees that it is necessary to clarify the treatment of PBM rebates and fees in the calculation of AMP. However, the Proposed Rule does not effectively accomplish this goal. That is, CMS fails to define the term "PBM" for the purpose of AMP calculations, which effectively allows manufacturers to include the sales from any entity that a manufacturer considers to be a PBM, including sales to managed care organizations, which are specifically excluded from AMP under the national rebate agreement.[14] We believe that CMS needs to clearly define the attributes of entities qualifying as PBMs for purposes of including price concessions from such entities and/or establish a list of excluded entities as we discussed in the section above. Doing so will enable

[12] See GAO, "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns About Rebates Paid to States," (GAO-05-102) (February 2005); see also OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063) (May 2006).
[13] 71 Fed. Reg. at 77179.
[14] Id.

manufacturers to use uniform criteria to distinguish between PBMs and non-PBMs for purposes of incorporating rebates and fees into AMP calculations. If, however, CMS fails to set forth guidance regarding PBMs, manufacturers will continue to treat PBM price concessions disparately, resulting in inconsistent AMP calculations across manufacturers. Therefore, it is imperative that CMS clearly identify factors that manufacturers should use in determining whether an entity is in fact a PBM.

As an additional matter, the Proposed Rule seems to include in the calculation of AMP PBM price concessions, but limits this inclusion to those rebates relating to PBM sales to the retail pharmacy class of trade.[15] If this is indeed CMS's intent, then the agency's proposal would not be practicable because manufacturers do not have information concerning these indirect sales. Manufacturers cannot ascertain whether PBMs' downstream sales are to the retail class of trade or not. Thus, they would not be able to ensure that their AMP calculations include only those price concessions related to sales to the retail pharmacy class of trade.

4. Identification of Sales

The Proposed Rule requires that AMP include only those sales to wholesalers "for dispensing to the general public," e.g., sales to wholesalers that result indirectly in sales to the retail pharmacy class of trade.[16] Often, however, a manufacturer will not know if the sale from a wholesaler is to an entity in the retail pharmacy class of trade. Generally, there are three types of direct sales involving manufacturers – direct sales to retail pharmacies, direct sales to wholesalers where wholesalers then sell to retail pharmacies, and direct sales to wholesalers where the wholesaler then sells to an entity that is unknown to the manufacturer. The third arrangement is the one that makes CMS' proposed policies operationally infeasible. That is, once a manufacturer sells to a wholesaler, the wholesaler may then sell to any number of entities.

Manufacturer sales data are captured at the wholesaler-manufacturer level, but any subsequent sale from the wholesaler could be to any entity – one that is either included or excluded from the retail class of trade. A manufacturer would have data to identify downstream indirect sales if they were processed by a wholesaler through a chargeback for a wholesaler program sale or a manufacturer-established contract sale. However, a manufacturer would not have sufficient data to identify indirect sales made by a wholesaler or distributor if a chargeback is not processed for the sale.[17] In the latter case, the manufacturer would not be able to identify the purchaser in the second sale or to assess whether the entity was in the retail pharmacy class of trade. This is also true of SPAP and Part D rebates, which we discuss below.

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[15] Id.

[16] Id.

[17] See Medicaid Drug Rebate Program Release #29 (acknowledging manufacturers' need to often recalculate or refine pricing data due to the improper inclusion or exclusion of certain sales.).

5. State Pharmaceutical Assistance Program ("SPAP") Rebates

As further clarification of the determination of AMP, CMS proposes to include SPAP price concessions in the calculation of AMP. CMS states that similar to the Medicaid program, Medicare Part D prescription drug plans ("PDPs"), Medicare Advantage prescription drug plans ("MA-PDs"), and SPAPs do not directly purchase drugs. Instead, SPAPs are generally third-party payers. Therefore, CMS believes that these sales should be included in AMP to the extent that the sales are to an entity included in the retail pharmacy class of trade. Accordingly, CMS proposes that SPAP sales, as well as rebates paid by the manufacturer to the SPAP, be included in the AMP calculation.

We, however, do not agree with CMS' proposed treatment of SPAP rebates. As CMS mentions, SPAPs are similar to the Medicaid program in that SPAPs represent third-party government payers. Therefore, because Medicaid rebates would be excluded from AMP calculations, the same should be true for SPAP rebates. SPAP data is only available on a quarterly basis with a considerable lag period and no correlation to a SPAP eligible sale. Manufacturers also have the opportunity to refile SPAP data for the quarterly reporting requirement. Accordingly, SPAP rebates should be excluded from monthly AMP calculations.

In addition, CMS' proposed treatment of SPAP rebates conflicts with the treatment required under previous CMS Manufacturer Release #68, which instructs manufacturers to distinguish between "qualified" and "unqualified" SPAPs, based on criteria listed in such release. Under this program release, only rebates to qualified SPAPs are excluded from AMP, whereas rebates to unqualified SPAPs are included in AMP. We request that CMS revisit this program release to address this inconsistency. If CMS ultimately decides to include all SPAP rebates in the calculation of AMP, then the agency should provide guidance regarding the method of inclusion.

6. Treatment of Medicare Part D Rebates

CMS proposes to clarify in the Proposed Rule that the treatment of prices of sales through a PDP, MA-PD, or a qualified retiree prescription drug plan for covered Medicare Part D drugs provided on behalf of Medicare Part D eligible individuals should be included in the AMP calculation. CMS states that similar to the Medicaid program, PDPs and MA-PDs do not directly purchase drugs, but are usually third-party payers. As is the case with Medicaid sales, CMS believes that these sales should be included in AMP to the extent that the sales are to the retail pharmacy class of trade. As such, CMS proposes that these prices, as well as rebates paid by manufacturers to the PDP or MA-PD, should be included in AMP calculations.

Similar to the discussion above concerning SPAP rebates, we recommend that CMS exclude Medicare Part D rebates from AMP calculations. Because Medicare Part D rebates are similar to Medicaid program rebates, which are excluded from AMP calculations, Medicare Part D rebates should be treated similarly.

Further, Medicare Part D rebates are excluded from best price, and the resulting inconsistent treatment of Medicare Part D prices in AMP and in best price calculations would be unjustified. As CMS acknowledges in the Proposed Rule, the law requires that "prices negotiated by a prescription drug plan, by an MA-PD plan . . . or by a qualified retiree prescription drug plan . . .with respect to such drugs on behalf of Medicare Part D eligible individuals, shall . . . not be taken into account for the purposes of establishing the best price...."[18] Because of this statutory mandate concerning best price, we believe CMS should treat Medicare Part D rebates in the context of AMP similarly to ensure parity for both AMP and best price calculations. Thus, we recommend that CMS use its authority to exclude Medicare Part D rebates from AMP.

7. Returned Goods

According to the Proposed Rule, CMS proposes to exclude returned goods from AMP calculations provided that such goods are returned in "good faith."[19] We recommend, however, that CMS clarify that products destroyed by purchasers (and, thus, not returned to the manufacturer) should be treated the same way as returned goods – e.g., excluded from AMP. Likewise, we recommend that recalls be treated the same as returned goods and excluded from AMP. We also urge CMS to clarify the treatment for AMP calculation of any return fees or reasonable recall fees paid by manufacturers.

8. Manufacturer Coupons

In the Proposed Rule, CMS proposes to clarify the way in which manufacturer coupons should be treated. CMS proposes to include coupons redeemed by any entity other than the consumer in the calculation of AMP. Accordingly, CMS proposes that coupons that are redeemed by the consumer directly to the manufacturer would not be included in AMP calculations. We recommend that CMS make clear that manufacturer coupons redeemed by a consumer, whether directly ***or indirectly*** to the manufacturer (e.g., through a pharmacy) should be excluded from AMP calculations.

9. Administrative and Service Fees

According to current policy under the Rebate Program, "administrative fees, which include service fees and distribution fees, incentives, promotional fees, chargebacks, and all discounts or rebates, other than rebates under the [Rebate Program]..." should be included in AMP calculations, provided those sales are to an entity included in the calculation of AMP. The OIG, however, noted that there is confusion among manufacturers regarding the treatment of

[18] 71 Fed. Reg. at 77183; see Social Security Act ("SSA") § 1927(c)(i)(VI); see also Medicaid Drug Rebate Program Release # 63 (Feb. 19, 2004).
[19] 71 Fed. Reg. at 77181.

such fees.[20] Given the OIG's report, CMS proposes to clarify the treatment of administrative fees by including all such fees in the calculation of AMP.

CMS proposes, however, to exclude from AMP fees paid for *bona fide* services. CMS proposes to define *bona fide* service fees as "fees paid by a manufacturer to an entity, which represent fair market value for a *bona fide*, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and which are not passed in whole or in part to a client or customer of an entity, regardless of whether the entity takes title to the drug."[21]

We strongly recommend that CMS clearly set forth guidance as to what constitutes a *bona fide* service fee. Although CMS attempts to make this clear in its proposed definition, it would be more helpful for CMS to provide additional parameters and/or specific examples to assist manufacturers in making this determination. Further, we encourage CMS to work with the OIG to establish a "safe harbor" for *bona fide* service fees. We believe that the payment of *bona fide* service fees by manufacturers could implicate the anti-kickback statute.[22] That is, *bona fide* service fees could be viewed as an incentive to purchase drug products from manufacturers. Given the potential for widely varying interpretations of the definition of *bona fide* service fees and the potential anti-kickback concerns, it is important that CMS and the OIG work together to provide clear guidelines and a safe harbor for this term.

B. Authorized Generics – Section 447.506

In the Proposed Rule, CMS proposes to require the primary manufacturer (NDA holder) to include, in its calculations of AMP and best price, sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary. CMS believes that to limit the applicability of the Proposed Rule to the sellers of authorized generic drugs would allow manufacturers to circumvent the intent of the DRA by licensing rather than selling the rights to such drugs. As is currently required, the secondary manufacturer or subsidiary of the brand manufacturer would continue to pay the single source or innovator multiple source rebate for the authorized generic products based on utilization under its own NDC number.

CMS, however, makes no mention in the Proposed Rule of sales from the brand manufacturer to the authorized generic manufacturer (e.g., sales at the "transfer price").[23] For purposes of consistency, we recommend that CMS also include the transfer price of the NDA holder to the authorized generic manufacturer in the NDA holder's best price calculations.

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[20] OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063) (May 2006).
[21] 71 Fed. Reg. at 77180.
[22] SSA § 1128B(b).
[23] DRA § 6003.

C. Requirements for Manufacturers – Section 447.510

In the Preamble, CMS sets forth the reporting requirements for manufacturers with regard to pricing data. Specifically, CMS proposes that AMP would be reported both on a monthly and quarterly basis to CMS. CMS proposes that the monthly AMP would be calculated using the same methodology as the quarterly AMP. In an effort to minimize the price fluctuations and to maximize the usefulness of the monthly AMP, CMS proposes to allow manufacturers to estimate the impact of their end-of-quarter rebates or other price concessions and to allocate these rebates or other price concessions throughout the quarter in the monthly AMPs reported to CMS. CMS invites comments on allowing the use of 12-month rolling average estimates of all lagged discounts for both the monthly and quarterly AMP. CMS also seeks comments on allowing manufacturers to calculate the monthly AMP based on updates of the most recent three-month period (i.e., a rolling three-month AMP).

While smoothing is a helpful mechanism to adjust for fluctuations in the calculation resulting from the timing of sales and credits, smoothing does not necessarily result in AMP bearing a more precise market price. Smoothing is dependent on historical data that may or may not be completely applicable to current business activity. However, in order to adjust for variability in monthly reporting periods, we agree with CMS' proposal to allow the "smoothing" of AMP data. In addition, we recommend that CMS permit four quarter smoothing to ensure a more consistent application of a percentage during the months of a quarter. We believe that this is a reasonable smoothing mechanism that would be beneficial to manufacturers and that would enhance the AMP data that are received by CMS.

D. Upper Limits for Multiple Source Drugs – Section 447.514

The currently reported AMP is based on the nine-digit NDC, combining all package sizes of the drug into the same computation. CMS proposed to continue this policy and solicited comments on the alternative approach of using 11-digit NDC to calculate AMP as well as comments on the merits of using both approaches in calculating AMP for the FUL calculation.[24]

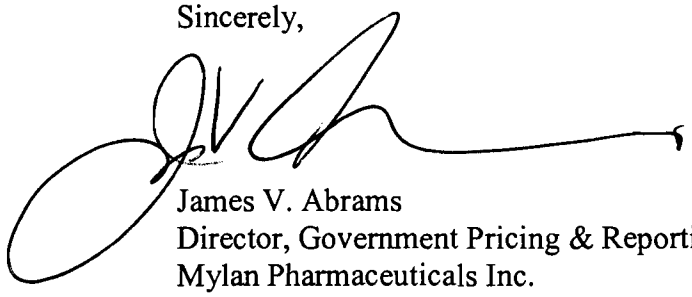
In response to CMS' request for comments on the appropriate NDC level for calculating AMP, we support the use of the 11-digit NDC. The primary benefit of the 11-digit NDC, as CMS notes, is the inclusion of package size in the AMP calculation. Also, CMS observes that the 11-digit NDC would align with the State Medicaid drug payments that are based on package size, as well as allow greater transparency. Further, taking into consideration different customer types, e.g., small and large retail pharmacies, and different life cycle management, applying the 11-digit NDC would promote greater consistency and accuracy among AMPs. Accordingly, we recommend the use of the 11-digit NDC for calculating AMP.[25]

[24] 71 Fed. Reg. at 77187.
[25] See 42 C.F.R. § 447.332(b)(2006).

III. Conclusion

In closing, Mylan looks forward to working with CMS as it finalizes these provisions of the Proposed Rule. If you have any questions or concerns, please do not hesitate to contact us.

Sincerely,



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February 20, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-2238-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore MD 21244-1850

Gentlemen:

Enclosed please find a copy of our electronic comment on CMS-2238-P, "Prescription Drugs". The comment was submitted electronically and we received comment number 111922 on February 20, 2007.

We submit this via overnight to assure that our comment is received by CMS. Please forgive our duplication.

Thank you for your attention to this comment.

Sincerely,

James V. Abrams
Director, Government Pricing & Reporting
James.abrams@mylanlabs.com
304-554-4089

Enclosure (1)

Department – Fax Numbers

Accounting	(304) 285-6403	Information Systems	(304) 285-6404	Purchasing	(304) 598-5401
Administration	(304) 599-7284	Label Control	(800) 848-0463	Quality Assurance	(304) 598-5407
Business Development	(304) 598-5419	Legal Services	(304) 598-5408	Quality Control	(304) 598-5409
Corporate Services	(304) 285-6482	Maintenance & Engineering	(304) 598-5411	Regulatory Affairs	(304) 285-6407
Human Resources	(304) 598-5406	Medical Unit	(304) 598-5445	Research & Development	(304) 285-6419
		Product Development	(304) 285-6411	Sales & Marketing	(304) 598-3232

Docket Management Comment Form

Docket: CMS-2238-P - Prescription Drugs

Temporary Comment Number: 111922

Submitter: Mr. James Abrams **Date:** 02/20/07

Organization: Mylan Pharmaceuticals Inc.

Category: Drug Industry

Issue Areas/Comments

General

See Attachment

Attachments

CMS-2238-P-T111922-Attach-1.doc

CMS-2238-P-T111922-Attach-2.doc

Print | Comment on Another Docket | Exit

Print - Print the comment

Exit - Leave the application

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Leading Light for Life

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–2238–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8015

VIA ELECTRONIC SUBMISSION AND EXPRESS MAIL
(http://www.cms.hhs.gov/eRulemaking)

Re: Comments on Proposed Rule related to the Medicaid Rebate Program, CMS-2238-P

Dear Ms. Norwalk:

Astellas Pharma US appreciates this opportunity to comment on the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) on December 22, 2006 implementing certain provisions of the Deficit Reduction Act of 2005 (DRA) relating to the Medicaid program.[1] Astellas is a global, research-based pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products that treat unmet medical needs. Our North American product lines focus on the therapeutic areas of immunology, cardiology, infectious disease, dermatology, and urology.

We appreciate the challenges involved in implementing the DRA, and commend CMS on its efforts in this area. We generally agree with the comments being submitted by the Pharmaceutical Research and Manufacturers of America, and we urge CMS to give careful consideration of the recommendations set forth in those comments. In our comments, we wish to focus in particular on the need to ensure adequate access to oral immunosuppressives at the pharmacy level for Medicaid transplant patients.

The DRA changed the federal upper limit (FUL) for multiple source drugs to 250% of the average manufacturer price (AMP) for the least costly drug in each multiple-source group.[2] CMS has proposed to use its rulemaking authority to establish safeguards to ensure that the FUL is set at a price that is "adequate . . . to ensure that a drug is available for sale nationally as presently provided in our regulations."[3] Specifically, CMS has proposed not to include in a FUL calculation: (1) the AMP of an NDC that has been terminated; or (2) an AMP that is less than 30 percent of the next highest AMP in the relevant multiple source drug group.[4]

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

[2] Social Security Act (SSA) § 1927(e)(5).

[3] 71 Fed. Reg. 77174, 77187 (Dec. 22, 2006).

[4] Id. at 77188. CMS proposed that the 30% outlier policy not apply when calculating the FUL for a multiple-source group that includes only the innovator and the first generic to enter the market.

We support CMS' proposal to establish these safeguards in the FUL methodology, and we believe an additional safeguard is warranted to ensure adequate access to anti-rejection immunosuppressives for Medicaid beneficiaries who have had organ transplants. Transplant patients must take immunosuppressives to prevent rejection of the transplanted organ, and access to these medications is critical. Missing even a few days of an anti-rejection immunosuppressive regimen can cause graft failure, resulting in loss of the organ and catastrophic consequences for the patient.

The special importance of access to immunosuppressives has prompted CMS to use its regulatory authority to establish safeguards for these therapies under Part D. CMS did this "because it was necessary . . . to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[5] This rationale applies equally in the Medicaid context, particularly in light of a recent report by the Government Accountability Office indicating that AMP-based FULs would result in Medicaid payment for many drugs that is substantially below pharmacy acquisition costs.[6]

We therefore urge CMS to establish an additional safeguard in the FUL methodology for immunosuppressives. Specifically, we propose that CMS base the FUL for immunosuppressive multiple-source drug groups on the lowest AMP that is not less than 70% of the next-highest AMP in the multiple-source drug group. In addition, we urge CMS to apply this safeguard to all anti-rejection immunosuppressive FULs, including FULs for multiple-source drug groups that only include the innovator drug and the first generic competitor.

* * *

Astellas appreciates your consideration of these comments, and would be pleased to provide any additional information that might be helpful to CMS as it prepares the final rule. Please contact me at 847-405-1640, or via email Michael.Ruggiero@us.astellas.com, if we can be of any assistance.

Sincerely,

Michael J. Ruggiero
Senior Director, Government Policy & External Affairs

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[5] Centers for Medicare & Medicaid Services, *Medicare Modernization Act 2007 Final Guidelines -- Formularies,* at 7.

[6] GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs (Dec. 22, 2006).

biogen idec

February 20, 2007

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

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

Dear Acting Administrator Norwalk:

Biogen Idec is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule published in the Federal Register on December 22, 2006 (the "Proposed Rule").[1] Biogen Idec is a global biotechnology company. Our research, development and products address a variety of key medical needs in the areas of oncology, neurology, and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, we transform scientific discoveries into advances in human health care.

Biogen Idec appreciates the additional clarity that CMS has provided in the Proposed Rule regarding the AMP and Best Price calculations and we support many of CMS' proposals. We comment, however, to highlight certain of those proposals that are of particular concern to us, as addressed in detail below. Biogen Idec also is a member of the Biotechnology Industry Organization (BIO), and we support those comments as well. We urge CMS to consider these comments and to implement them in the Final Rule.

I. CMS Should Revise the Proposed Treatment of Manufacturer Coupons

The Proposed Rule excludes from the determination of AMP and Best Price manufacturer coupons "redeemed by a consumer,"[2] but directs that those coupons that are redeemed by an entity other than the consumer are to be included in AMP and Best Price.[3] In the preamble to the Proposed Rule, CMS suggests that the basis for this distinction is CMS' belief that coupons redeemed to the manufacturer by an entity other than the consumer, such as a retail pharmacy, will ultimately affect the price paid for the manufacturer's product by that entity.[4] Biogen Idec believes that this approach incorrectly assumes that all such indirect redemption arrangements necessarily affect the price realized by the redeeming pharmacy. Biogen Idec urges CMS to revise its proposed policy on manufacturer coupons to make clear that only arrangements that affect the price realized must be included in AMP and Best Price. Biogen Idec is concerned that the current proposal, in the absence of such a clarification, will

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

2 Id. at 77,197 (proposed 42 C.F.R. §§ 447.504(h)(9); 447.505(d)(8)).

3 Id. (proposed 42 C.F.R. §§ 447.504(g)(11); 447.505(c)(12)

4 Id. at 77,183.

inappropriately require the inclusion in AMP and BP of coupon programs that do not affect realized prices, distort those price figures, and create a disincentive for manufacturers to continue offering these valuable programs.

This point can be illustrated in relation to consumer coupons for free goods (e.g., a one month free supply of product), which provide patients with drug product at no cost. Where the product is an injectible product, as is the case with Biogen Idec's products, it is often administratively more efficient for a manufacturer to engage a specialty pharmacy to process such coupons and ship the free product to the consumer, rather than having the manufacturer fulfill the coupon itself. In such circumstances, the manufacturer may provide the pharmacy with consigned inventory to use in fulfilling the coupons, or alternatively, the manufacturer may choose to have the pharmacy use its own purchased product to fulfill the coupon but then provide the pharmacy with replacement product. In both cases, the manufacturer also would pay the pharmacy a bona fide service fee for administering the program. Neither the consignment arrangement nor the replacement product approach affects the price realized by the pharmacy: in the case of consigned product, the pharmacy never purchases the product at issue, and in the case of replacement product, the pharmacy receives in kind exactly that which it dispensed. Finally, the fee itself by definition would not affect the price realized where it satisfies the definition of a bona fide service fee. Biogen Idec recommends that CMS make clear in the Final Rule that where a free goods coupon is redeemed through a pharmacy that either uses consigned product or its own product but receives replacement product, plus a bona fide service fee, the transaction may be excluded from the manufacturer's AMP and Best Price calculations.

II. CMS Should Clarify Whether Physician Offices and Home Health Care Providers Are in the Retail Class of Trade

The Proposed Rule defines the retail pharmacy class of trade as "any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[5] Biogen Idec believes that this proposed definition will provide valuable clarity to industry and will aid in the standardization of manufacturers' AMP calculations. We request, however, that CMS specify in the Final Rule whether physician offices and home health care providers[6] meet the new retail definition. Although Biogen Idec appreciates that CMS cannot address the retail status of each purchasing entity, we believe that it is important that CMS specifically address physician offices and home health care providers, each of which may account for a portion of a manufacturer's sales.

III. CMS Should Adopt the ASP Smoothing Methodology for the Clarification of Monthly and Quarterly AMP

Under the Deficit Reduction Act of 2005 ("DRA"), manufacturers must now report AMP to CMS on a monthly basis, in addition to submitting their quarterly AMP and Best Price reports.[7] CMS has proposed that manufacturers calculate their monthly AMP in the same manner as their quarterly AMP, except that monthly AMPs would not be subject to revision

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[5] Id. at 77,196 (proposed 42 C.F.R. § 447.504(e)).

[6] Home healthcare providers typically are specialty pharmacies that provide for the home delivery and administration of product by health care professionals.

[7] DRA §6001, Pub. L. No. 109-171.

more than 30 days after the month.[8] As monthly AMPs would not be subject to restatement, CMS has requested comments on the appropriate smoothing methodology to use in that calculation to estimate lagged data, and Biogen Idec urges CMS to adopt the methodology currently used for the Average Sales Price (ASP) calculation. We also urge CMS to permit manufacturers to derive their quarterly AMP figures from a weighted-average of the monthly AMPs in the quarter, to ensure consistency in these two sets of data.

1. CMS Should Adopt the ASP Smoothing Methodology for the Calculation of Monthly AMP Figures.

CMS has invited comment on allowing the use of 12-month rolling average estimates of all lagged discounts to smooth monthly AMP calculations.[9] Biogen Idec strongly recommends that CMS adopt the same methodology for estimating end-of-quarter rebates and other lagged discounts that it adopted for purposes of smoothing lagged ASP-eligible price concessions. CMS first finalized this requirement in September 2004,[10] but also included an extensive discussion of this issue in its 2007 PFS Final Rule.[11] This methodology already has been subject to review and comment by industry, and we believe that building upon this prior learning will ease implementation for both CMS and manufacturers.

The ASP smoothing methodology requires manufacturers to estimate lagged eligible price concessions using a ratio of lagged ASP-eligible price concessions for the most recent 12-month period to ASP-eligible sales for the same period.[12] This same approach can be used to smooth monthly AMP figures by calculating the ratio of lagged AMP-eligible price concessions for the most recent 12-month period to AMP-eligible sales for the same period, and applying it to the AMP-eligible sales in the month. Permitting manufacturers to use the same methodology for both AMP and ASP smoothing calculations will minimize the operational burdens on manufacturers that sell Medicare Part B drugs and would reduce the risk of error associated with using two different calculation methodologies. We believe that this approach also would reduce volatility in the monthly pricing data, which will be critical for States that use these figures to set pharmacy reimbursement rates.

As CMS is aware, the 2007 PFS Final Rule did not mandate the use of a particular formula to estimate lagged ASP-exempt sales. For the same reasons outlined above, we believe that CMS should permit manufacturers to use the methodology they currently use to estimate lagged ASP-exempt sales to smooth lagged AMP-ineligible sales.[13] If CMS were to adopt a particular methodology in the ASP context, manufacturers could apply that same approach for purposes of AMP.

2. Manufacturers Should be Permitted to Calculate Quarterly AMP Based on the Weighted Average of Monthly AMPs in the Quarter

While CMS has proposed to prohibit the restatement of monthly AMP figures,[14] the Proposed Rule provides that manufacturers still would be obligated to restate quarterly AMP

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8 71 Fed. Reg. at 77,186.

9 Id. at 77,186.

10 69 Fed. Reg. 55,763 (Sept. 16, 2004) (codified at 42 C.F.R. § 414.804(a)(3)).

11 PFS Final Rule, 71 Fed. Reg. at 69,787.

12 Id.

13 PFS Final Rule, 71 Fed. Reg. at 69,671.

14 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. § 447.510(d)(3)).

during the 12 quarter period prescribed by regulation.[15] CMS did, however, request comment as to whether manufacturers instead should be permitted to smooth lagged data for their quarterly AMP calculation.[16] In response to that request, Biogen Idec requests that CMS permit, but not require, manufacturers to calculate the quarterly AMP based on a weighted average of the three monthly AMPs for the quarter, and to make clear that manufacturers that select this option would not be required to restate their quarterly AMP, other than to correct an error.

Use of a weighted average of monthly AMPs to calculate quarterly AMP would account for lagged price concessions, because each monthly AMP calculation would include an estimate of such transactions. This approach also would minimize discrepancies between monthly AMP submissions and quarterly AMP submissions, which is particularly important in light of the fact that CMS proposed to make both monthly and quarterly AMP figures publicly available and States may use either the monthly or quarterly AMP figures for pharmacy reimbursement. An alternative approach, whereby the monthly AMP calculation is smoothed and the quarterly AMP is restated, could create inconsistencies between monthly and quarterly AMP data and, as a result, disparities in pharmacy reimbursement rates across States. Manufacturers would save the administrative expense of restating their quarterly AMP submissions, and State Medicaid programs and CMS would avoid the administrative burden associated with processing reconciliation statements. Finally, this approach would reduce the risk of error in AMP calculations because manufacturers would not be using two separate methodologies for their monthly and quarterly AMP calculations.

IV. Biogen Idec Supports the Inclusion of Discounts to Pharmacy Benefit Managers (PBMs) in Best Price

CMS has proposed to include in Best Price "PBM rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs."[17] As CMS noted in the preamble to the Proposed Rule, PBMs often receive rebates, discounts or other price concessions which directly or indirectly adjust prices, and excluding these discounts could result in an artificial inflation of Best Price.[18] Biogen Idec agrees that discounts and price concessions to PBMs, which would not include administrative fees that qualify as bona fide service fees, should be included in Best Price calculations and we recommend that CMS finalize this proposal.

V. CMS Should Ensure that the Definition of AMP Represents A Price at Which Retail Pharmacies Can Actually Purchase

The DRA amendments, effective January 1, 2007, require that CMS make AMP data publicly available.[19] In the preamble to the Proposed Rule, CMS states its belief that these provisions demonstrate that "Congress intended that States have drug pricing data based on actual prices," as compared to prior data "that did not necessarily reflect actual manufacturer prices of sales to the retail class of trade."[20] Biogen Idec agrees that it is critically important for States to have drug pricing data that accurately reflects the actual price of the drug to the retail

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15 Id. (proposed 42 C.F.R. § 447.510(b)).

16 Id. at 77,186.

17 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. § 447.505(c)(2)

18 71 Fed. Reg. at 77,182.

19 DRA § 6001(a)(2) (codified as Social Security Act § 1927(e)(5)).

20 71 Fed. Reg. at 77,178.

class of trade, but urges CMS to ensure that the AMP data reflect the prices at which retail pharmacies are able to acquire product.

The Proposed Rule directs manufacturers to include in AMP discounts to non-purchasers such as PBMs, Part D plans, and state pharmaceutical assistance programs (SPAPs). As CMS has noted in the context of PBM discounts, manufacturers do not always know what portion, if any, of these discounts are passed on by these payers to the pharmacies that actually purchase and dispense the product.[21] Biogen Idec is concerned that if AMP is calculated to include discounts that payers do not share with retail pharmacies, then any AMP-based reimbursement rates would fail to reimburse retail pharmacies for their full acquisition costs. In the case of single source drugs, this may create an incentive for pharmacies to seek physician approval to switch patients to competing products that are not therapeutically equivalent but that have more favorable reimbursement rates. Moreover, if retail pharmacies decline to stock certain products because the AMP-based payment rate is too low, AMP-based reimbursement may result in limited access to needed therapies for Medicaid beneficiaries. It is critically important that CMS remain sensitive to these issues as it finalizes the Proposed Rule.

VI. CMS Should Make Explicit that the Proposed Rule is Prospective Only and Should Provide Manufacturers a One Year Period to Implement the Final Rule

The implementation of CMS' proposed changes to current Medicaid drug rebate policy may require a substantial investment of time and effort by manufacturers. Manufacturers will need to train their staff on the new calculation methodologies, upgrade and transition their existing Medicaid price reporting systems, and collect and submit new data elements. In light of the significant departure from current AMP and Best Price calculation policies, Biogen Idec asks that CMS provide manufacturers four quarters to fully implement the requirements of the Proposed Rule after it is made Final. We further request that CMS set forth explicitly that the proposed changes apply to Medicaid price calculations only as of the effective date of the Final Rule and are not being implemented retrospectively.

* * *

Biogen Idec appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at 202-383-1443 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

Dee Simons
Director Government Reimbursement Policy
Biogen IDEC, Inc.
801 Pennsylvania Avenue, N.W.
Suite 710
Washington, D.C. 20004

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[21] 71 Fed. Reg. 77,179.

79

Mu Hyk Submissions

MIAMI INFUSION and PHARMACY, INC.
7150 WEST 20TH AVENUE, SUITE M-129
HIALEAH, FLORIDA 33016
305-558-7523

February 16, 2007

To whom it may concern

Miami Infusion and Pharmacy is an independent pharmacy operating in the state of Florida. These independent pharmacies provide prescription products and services to Medicaid and Medicare patients in urban, suburban, inner cities and rural communities. Prescription products and professional services are also provided to non-Medicaid and Medicare patients through contractual agreements with regional and national health plans and various governmental organizations. The UNITED DRUGS cooperative negotiates and administers these agreements on behalf of its member pharmacies. Additionally the cooperative negotiates and administers a purchasing contract with one national drug wholesaler whereby member pharmacies must purchase over 90% of their innovator multi source drug (brand) and multi source drug (generic) products:

Definition of Retail Pharmacy Class of Trade and Determination of AMP.

CMS believes, based in part on the OIG and GAO reports, that sales and discounts to mail order pharmacies shall be included in the AMP price calculation along with independent and chain retail pharmacies.

Retail Pharmacy class of Trade means that sector of the drug marketplace, which dispenses drugs to the general public and which includes all price concessions (except prompt pay discounts) related to such goods and services. CMS proposes to exclude from AMP the prices of sales to nursing home pharmacies. CMS will include in AMP the prices of sales and discounts to mail order pharmacies. Inclusion of these lower mail order pharmacy prices would decrease AMP, thereby decreasing manufacturers current rebate liabilities the State Medicaid programs and other entities.

Comments:

Mail order pharmacies should be excluded for the following reasons:

1. All major mail order pharmacies in the USA are owned by PBM's. The alignment of the PBM, its customers and their mail order division permits them to leverage manufacturers for substantial rebates which are not available to retail pharmacies.

2. CMS state that the exclusion of mail order and PBM prices would substantially reduce the number of transactions included in AMP. Mail order pharmacies provide some prescriptions to Medicaid patients. PBM mail order companies provide approximately 20% of the prescriptions dispensed to the non-Medicaid market.

3. Mail order pharmacies favor the purchase in very large package sizes (NDC-11) yielding the lowest per unit price in the marketplace. These package sizes are neither accessible to nor feasible in a typical independent retail pharmacy due to smaller sales volume,

inventory management and return investment factors. It is not economically feasible for small independent pharmacies to purchase large package sizes as a standard operation.

4. PBM's operate mail order facilities in the U.S.A. and the earn certain rebates, discounts and other price concessions that are not available to retail pharmacies. Inclusion of PBM price concession in the calculation of AMP places retail pharmacies at a significant price disadvantage because these price concessions are not available to independent pharmacies.

5. PBM's do not distribute drugs except through their privately owned mail order facilities. Drugs dispensed and distributed through retail pharmacies are purchased and owned by the retail entities. PBM's "credit" their sales revenues as if they own the inventory, but they do not. Rebates earned by a PBM for sales of drugs at the independent retail pharmacy are not, in any fashion, shared with the pharmacy.

6. PBM's are not wholesale distributors therefore there is no method for distributing these lower cost drugs to the retail sector:

   As a result mail order pricing should NOT be considered in the AMP calculations.

Conclusion:
If the Final Rule permits the inclusion of mail order pricing in the calculation of AMP then these mail order pharmacies will have an unfair competitive advantage over retail pharmacy where 80% of consumers currently access these products.

Determination of Best Price.

CMS proposes that best price be calculated for single source or innovator multiple source drugs to include all sales, discounts, and other price concessions provided by the manufacturer can demonstrate that the sale, discount, or other price concession is specifically excluded by statue or is provided to an entity not included in the rebate calculation. To the extent that an entity is not in included in the best calculation, both sales and associated discounts or other price concessions provided to such an entity should be excluded from the calculation.

OIG recommended that CMS clarify the treatment of all PBM rebates. The documents states that manufacturers do not know what part of these discounts are kept by the PBM and what part is passed on to the insurer or other entity and what part that PBM entity passes on to pharmacies. Additionally CMS states that PBM's have assumed significant role in drug distribution.

Our organization Miami Infusion and Pharmacy has contractual agreements with nearly all of the PBM's in the USA and no (zero) PBM rebates or other price concessions or discounts are shared with Miami Infusion and Pharmacy or its network of Pharmacies. Therefore, these discounts must be excluded from any calculation of Best Price or require the PBM's to relinquish their rebates to retail pharmacy.

Exclusion from Best Price of certain sales at a Nominal Price

The national rebate agreements permit manufacturers to exclude from their Best Price calculation outpatient drug prices below 10% of the AMP. CMS is proposing to define Nominal Price as prices at less than 10% of the AMP in the same quarter only when certain safety net providers are the purchasers. These safety net providers include: federally qualified health centers, (340B); certain family

planning projects; HIV / AIDS programs, black lung clinics, hemophilia centers, Native Hawaiian Health Centers, urban Indian organizations, sexually transmitted disease treatments, TB, and mental retardation (ICF /MR) programs. CMS recognizes that Nominal Price exclusion will continue to be used as a marketing tool. Historically, patients frequently remain on the same drug regimen following discharge from a hospital (or safety net provider).

Comments.

Nominal Priced products should be excluded from Best Price calculations because these prices are not in any way representative of the acquisition costs available to retail pharmacies.

Aggregate Upper Limits of Payment (aka: FUL)

Upper Limits for Multiple Source Drugs

The DRA (effective January 1, 2007) states that a FUL must be established for each Multi-Source drug for which the FDA has rated two or more products as therapeutically equivalent.

Currently CMS selects the lowest price (AWP, WAC or direct cost) from among the A rated formulations and drugs not proven to be therapeutically equivalent (B rated drugs) and applies the formula described in 447.332 (150% of published price) to determine the FUL for the drug.

Effective January 1, 2007 the FUL for Multi-Source drugs shall be established at 250% of the AMP for the least costly therapeutic equivalent. Calculation of AMP will be at the nine-digit NDC thereby combining all package sizes of the drug into the same computation.

CMS believes that computing the AMP at the 11-digit NDC would not be significantly more than computing the AMP at the 9-digit level. State Medicaid payments are computed at the 11-digit NDC.

CMS believes that computing FUL at AMP times 250% is sufficient pharmacy reimbursement for the drug regardless of the package size the pharmacy purchases.

According to a national study released on February 1, 2007 by the Coalition for Community Pharmacy Action (CCPA) the national average cost of dispensing medication is $10.50 per prescription, which is in addition to the ingredient cost of the drug. In order to remain profitable and to deliver prescription services to millions of scan citizens Medicaid reimbursement must be adequate to permit the continuation of this service. Currently dependent pharmacies dispense multi-source generic prescriptions at a rate of 55% to 70% of all prescriptions. In other words, up to seven out of ten prescriptions are generics. Implementation of the proposed CMS AMP rule will devastate the financial viability of independent community pharmacy.

Conclusion

The inclusion of manufacturer rebates and price concessions in the calculation of AMP clearly benefits manufacturer and disadvantages independent pharmacies because these price reductions are not shared with independents yet they are added into the cost of multi-source drugs paid by independent pharmacies.

Independent pharmacies serve nearly 40% of the marketplace for their prescription needs. We are unique in our level of patient service where satisfaction levels are the highest in the entire health care industry. We are also the only prescription provider in rural America and in the majority of urban population centers.

Independent pharmacies purchase their drugs from wholesalers under contractual agreements that link a pharmacy to a wholesale: for 90-95% of their purchases.

Independent pharmacies do not have the ability to move their purchasing to another wholesaler or supplier if one of these entities has a "lower" priced generic.

Availability of the lowest price Generic drugs must be universal or the AMP Pricing rule will place independent pharmacy at a competitive disadvantage. Availability must also mean that "stock is on hand', not just listed in a data base as available.

CMS proposes to include FDA V" rated drugs in the calculation. With this inclusion the Department of Health and Human Services must indemnify retail pharmacies from any harmful affects resulting from the utilization of these FDA declared substandard drugs.

If CMS is unwilling to modify the inclusion of rebates and price concessions in their calculation of AMP then CMS should include a Minimum Margin for low cost generic drugs for independent pharmacies. The minimum margin must, at the very least, cover the cost of dispensing.

CMS suggests, without mandate, that states should amend their dispensing Fees to modify the AMP impact. This is unlikely due to federal payment reductions to state Medicaid programs and budget constraints at the state level.

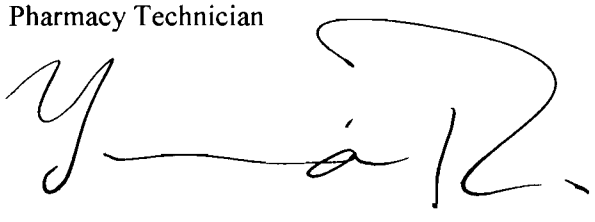
Additionally many states have implemented a managed care model for Medicaid patients. Prescriptions dispensed under this model will utilize AMP, but will not modify dispending fees due to the capitated agreements.

The majority of managed Medicaid programs are administered by PBM's under the proposed rules discussed in this document. CMS is rewarding the PBM's and their mail order businesses because of their access to rebates and other manufacturer price concessions.

Respectfully Submitted,

Yesenia Rodriguez

Pharmacy Technician



OUTLOOK CLINIC

OUTLOOK HEALTH SERVICES, INC.

P.O. Box 320 • North Branch, MN 55056 651-674-4570

February 20, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the Executive Director of Outlook Clinic, a non-profit organization that provides low cost birth control, STD services and pregnancy testing in four clinics in East Central Minnesota.

Outlook Clinic served over 1750 patients last year, most of whom could not otherwise afford the health services—particularly oral contraceptives—that we provide. For over twenty-two years, Outlook Clinic has been committed to providing low-income women and families living in East Central Minnesota high-quality reproductive health care and affordable birth control. Most of our patients are low-income:

- 89% of Outlook Clinic's patients live below 200% of the federal poverty level, in fact,
- 80% of Outlook Clinic's patients live below 150% of the federal poverty level.

Outlook Clinic operates with a sliding fee scale based on income, and since most of our patients are poor they pay, on average, $5.00 to $25.00 for a physical exam and $4.00 a month for a packet of birth control pills. In the past we've been able to serve women in need because we have been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. *Without this ability, Outlook Clinic will struggle significantly to keep serving our patients and, in fact, may not be able to keep all of our clinics open.*

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Outlook Clinic is not federally funded and therefore does not qualify as a 340B covered entity. Nonetheless, we are an essential safety net provider in our community.

We at Outlook Clinic sincerely hope that the Centers for Medicare and Medicaid Services (CMS) will exercise its authority to name "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. Under a 'safety net provider' definition we are confident Outlook Clinic would qualify, and, therefore, be able to provide essential health care services, including low-cost birth control pills, to our patients. I strongly urge CMS to include in its definition of 'safety net providers', nonprofit, outpatient clinics like ours.

Respectfully submitted by,

Betty Nelson

Betty Nelson, Director
Outlook Clinic
P.O. Box 320
North Branch, MN 55056

Judy's Drug Store, Inc

24 North Main St., Petersburg, WV 26847 • 304-257-1044

February 16, 2007

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

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

I am pleased to submit theses comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located in **West Virginia**. We are a major provider of pharmacy service in the community and your consideration of theses comments is essential.

1. **Remove PBM and Mail Order from Retail Class of Trade**
   - Creates consistency in the Regulation
   - Conforms definition with market reality

2. **Implement a Trigger Mechanism**
   - Addresses severe price fluctuations
   - Reduces risk of Market Manipulation
   - Mitigates Risk of Pricing Lag

3. **Use of 11-Digit NDC versus 9-Digit NDC**
   - Represents the most common package size dispensed by retail pharmacies

Sincerely,

Emily C. Judy, PharmD

cc:
Senator Robert C. Byrd (D-WV)
Senator John D. Rockefeller (D-WV)
Representative Alan B. Mollohan (D-01)
Representative Shelley Moore Capito (R-02)
Representative Nick Joe Rahall, II (D-03)

SAV-ON DRUGS, INC.
P.O. BOX 163
345 BROAD STREET
COLUMBIA, MS 39429

February 15, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy(s) is located ___ We are a major provider of pharmacy service in the community and your consideration of these comments is essential.

SAV-ON-DRUGS

1. Definition of "Retail Class of Trade" – Removal of PBMs and Mail Order Pharmacies

Excluding PBMs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the "general public." The more extensive comments submitted by the Mississippi Independent Pharmacies Association has addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP- Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent

3. Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize the Medicaid pricing is heavily regulated by the state and federal governments.

4. Manufacturer Data Reporting for Price Determination – Address Market Lag And Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns the Mississippi Independent Pharmacies Association proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer reporting error.

5. Use of 11- Digit NDC versus 9- Digit NDC

We believe that CMS should use the 11- digit AMP value for the most commonly dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules of the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion I support the more extensive comments that are being filled by the Mississippi Independent Pharmacies Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,
Your Name
Deborah McDaniel R.Ph.
Deborah McDaniel
2-15-07

SAV-ON DRUGS, INC.
P.O. BOX 163
345 BROAD STREET
COLUMBIA, MS 39429

02-14-07

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

Ms. Norwalk,

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

As I am sure you are well aware, pharmacy services are an integral part of the health care of all Americans, but especially important to the health care of the poor, indigent, or others who qualify for state Medicaid assistance. This population may be at an increased risk of poor health care due to various influences, and often, pharmacy services, such as prescriptions, may be on of the most efficient and influential accesses for the recipient.

Unfortunately, quality health care does come with a cost, and the pharmacy piece is no different. If CMS-2238-P is implemented in its current form, my pharmacy will be reimbursed below the cost of acquisition for the medication. This does not consider the recently released report from the accounting firm Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies in which it is reported that the median cost of dispensing a prescription for a pharmacy is $10.51.

My concerns are further supported by the GAO's report that states that community pharmacies, such as mine, will lose an average of 36% on each generic prescription filled for Medicaid recipients. My pharmacy will not be able to fill Medicaid prescriptions under such an environment.

Pharmacists save money for state Medicaid agencies, CMS, and this country. If the AMP is not defined fairly, from a retail pharmacy perspective, and if the GAO report is accurate, many pharmacies, including my pharmacy, will be unable to fill Medicaid prescriptions or will cease to exist. This in turn will decrease access for the Medicaid recipient and will increase the costs for Medicaid and this country far above any savings that are to be realized through AMP pricing for generic prescriptions.

Sincerely,

Clark T. Astin RPh
Clark's Pharmacy, Boaz, AL 35957

February 15, 2007

84.

Centers for Medicare & Medical Services
Re: (AMP)

Retail pharmacies are currently reimbursed at inadequate levels and now face AMP, a rate that on average is 36% below acquisition cost. This, if passed with the current formula, will put the final nail in our coffin. The AMP was never intended to serve as a basis of reimbursement.To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by: 1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy. 2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way as retail pharmacies. 3. Reporting AMP at the 11 - digit level to ensure accuracy.

If CMS is going to proceed with AMP, I would like to propose a flat fee of at least $18.00 per prescription to dispensing pharmacies and a mandatory generic substitution in all categories. Furthermore, a generic therapeutic equivalent for single source brands in most categories. There are currenty generic drugs in almost every therapeutic category. Provide a formulary to all pharmacies willing to enter this plan. I guarantee we can save money. The fee should cover the pharmacy for the extra time and effort and phone calls to the physician. This program will work! CMS will save money! And retail pharmacy will have a chance to survive and continue to serve the great citizens in our communities!

I am certainly available for any comments or questions in this matter. This is a matter of life and death in our community pharmacy. Give pharmacists a chance and we will turn this whole mess around. With this plan PBM's can go back to processing claims instead of steering drugs and money in a way that benifits themselves and the mail order houses, and then maybe a level playing field can be formed so everyone, most importantly the people, can all get a fair shake, while still saving Medicare and Medicaid money!

Sincerly yours,

L.Clark Boyd, 3rd. RPh
President
Boyd's Pharmacy
(609)499-0100

February 2, 2007

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

Ms. Norwalk,

I am writing you to comment on the proposed rule (CMS-2238-P) regarding the reimbursement of pharmacy providers based on the AMP model as set forth in the Deficit Reduction Act of 2005.

Pharmacy services are an integral part of the health care of all Americans, but especially important to the health care of the poor, indigent, or others who qualify for state Medicaid assistance. We counsel and advise this population several times a day. Several of these patients tell us they trust us more than their doctors and we are much more accessible.

Unfortunately, quality health care does come with a cost, and the pharmacy piece is no different. If CMS-2238-P is implemented in its current form, my pharmacy will be reimbursed below the cost of acquisition for the medication. This does not consider the recently released report from the accounting firm Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies in which it is reported that the median cost of dispensing a prescription for a pharmacy is $9.86.

My concerns are further supported by the GAO's report that states that community pharmacies, such as mine, will lose an average of 36% on each generic prescription filled for Medicaid recipients. My pharmacy will not be able to fill Medicaid prescriptions under such an environment. We average 1500 medicaid prescriptions a month at our pharmacy for an average of 16% of our total prescription volume.

Pharmacists save money for state Medicaid agencies, CMS, and this country. If the AMP is not defined fairly, from a retail pharmacy perspective, and if the GAO report is accurate, many pharmacies, including my pharmacy, will be unable to fill Medicaid prescriptions or will cease to exist. This in turn will decrease access for the Medicaid recipient and will increase the costs for Medicaid and this country far above any savings that are to be realized through AMP pricing for generic prescriptions.

Sincerely,

DeAnne Pace, Pharm.D., CGP

February 16, 2007

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

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

Dear Ms. Norwalk:

As President and on behalf of the Navajo Nation, I am providing comments to the proposed regulations, published in the Federal Register on December 22, 2006, at Vol. 71, No. 246, implementing provisions of the Deficit Reduction Act (DRA) pertaining to prescription drugs under the Medicaid program.

It is our understanding that this proposed rule, in part, will limit State Medicaid expenditures for certain multiple source drugs. States will retain the authority to set their own reimbursement levels and dispensing fees paid to pharmacists, and may pay above or below the Federal upper payment limit (FUL) as long as overall payments for drugs subject to a FUL are under the annual aggregate cap. About 600 drugs are initially subject to the FULs, including drugs for the treatment of asthma, hypertension, pain relief, and depression. States can vary reimbursement levels and can, for example, target more favorable reimbursement to pharmacists in rural or inner city areas or to independent pharmacists. To implement these regulations, each State must amend their State Medicaid Plan and describe their approach.

The Indian Health Service (IHS) and tribally operated pharmacies have authority to dispense, bill, and receive reimbursement from State Medicaid agencies for drugs prescribed to Medicaid beneficiaries. The State Medicaid agencies reimburse IHS and tribal pharmacies at cost per a payment methodology outlined in the State plan. IHS and tribal programs depend on the Medicaid reimbursements to supplement existing IHS appropriations to the IHS and tribal programs that are currently under funded. Many of these pharmacies are small and operate in remote rural areas. As such, any changes in Medicaid reimbursements can have a negative effect on their financial sustainability. The complexities of Indian health financing make it imperative that States consult with Tribes before and during the development of any amendments to their state plans. Without this consultation, implementation of this rule may have unintended negative consequences on Indian health programs.

On November 9, 2006, Mr. Dennis Smith, Director, Centers for Medicaid and State Operations issued a letter (SMDL #06-023) to the State Medicaid Directors encouraging States to consult with Indian Tribes when implementing the Deficit Reduction Act and submitting State Medicaid plan amendments. The letter specifically states:

> "In light of the new Deficit Reduction Act of 2005 (DRA) and our continued desire for Medicaid programs to effectively serve Tribal communities, CMS is taking this opportunity to again encourage States to consult with Tribes in open, good faith dialogue, as a number of provisions within the DRA have the potential to impact Tribes and American Indian and Alaska Native (AI/AN) Medicaid beneficiaries. Given the States' new flexibility to change their Medicaid programs through State Medicaid plans rather than through Medicaid demonstrations, maintaining ongoing communication between States and Tribes in the redesign of Medicaid programs and services is even more important...CMS strongly encourages all States to consult with Tribes as they implement the DRA."

Consistent with CMS policy, we are requesting that CMS insert language in the final rule that would specifically remind States to consult with Indian Tribes in the development of any State plan amendment to modify existing payment methodologies for prescription drug reimbursements. This reminder will allow each Indian Tribe the opportunity to work with the State to assess local impacts and identify options prior to submission of State Plan amendments.

We are also requesting that CMS insert language in the final rule to encourage States to maintain their current level/type of reimbursement and filling fees to Tribal and IHS pharmacies because they are important safety net providers and will be harmed by the reductions. Because of the limited capacity of many Tribal and IHS pharmacies, and their dependence on prescription drug reimbursements to meet overhead and administrative costs, we believe that implementation of this proposed rule will result in Tribal and IHS pharmacies shouldering a disproportionate share of Medicaid prescription drug reductions. Tribal and IHS providers should be explicitly recognized as essential safety net pharmacies.

On behalf of the Navajo Nation, I appreciate the opportunity to comment on these rules.

Sincerely,

Dr. Joe Shirley, Jr., President
THE NAVAJO NATION

cc: Ben Shelly, Navajo Nation Vice President
Patrick Sandoval, Chief of Staff, Office of the President and the Vice President
Anslem Roanhorse, Jr., Executive Director, Navajo Division of Health
John Hubbard, Area Director, Navajo Area Indian Health Service

AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

February 15, 2007

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

Re: Comments on Proposed Rule Implementing Average Manufacturer Price Under Medicaid

Dear Ms. Norwalk:

The American Society of Consultant Pharmacists (ASCP) is pleased to submit the following comments regarding the notice of proposed rulemaking implementing a new federal upper limit (FUL) for multiple source medications under Medicaid based upon average manufacturer's price (AMP).

ASCP is the international professional society that provides leadership, education, advocacy and resources to advance the practice of senior care pharmacy. ASCP's 8,000 members manage and improve drug therapy and improve the quality of life for geriatric patients and other individuals residing in a variety of environments, including nursing facilities, sub-acute care and assisted living facilities, psychiatric hospitals, hospice programs and in home and community-based care.

While many of the elderly patients our members serve are now participating in the new Medicare Part D prescription drug program, there are some who continue to receive Medicaid drug benefits. In addition, most Medicaid programs provide coverage for medications that are excluded from Part D coverage. As such, we are concerned that the recent proposed rule to implement federal upper limits based upon average manufacturer price (AMP) will adversely affect pharmacies that continue to serve Medicaid patients.

According to the proposed rule, CMS has defined AMP as the price paid by wholesalers for drugs distributed through the retail class of trade. As such, medications purchased by long-term care pharmacies are not included in the AMP calculation. ASCP agrees with CMS that these medications would be inappropriate to include in AMP calculation. However, we believe there are other price concessions not available to pharmacies that should also be excluded from AMP calculation. For example, mail order discounts and discounts to other entities such

as pharmacy benefit managers (PBMs) are generally not passed on to pharmacies. Our concern is that if these price concessions are included in AMP, the resulting baseline AMP will be artificially low.

Further, we are deeply concerned about the impact this is likely to have on smaller, independent pharmacies that serve Medicaid patients. Our concern is that under the proposed rule, pharmacy acquisition costs may exceed reimbursement levels, especially with respect to independent pharmacies. Many of these smaller, independent pharmacies do not have the cash flow to continue operating at a loss, and may either stop serving Medicaid patients, or close their doors altogether. ASCP is concerned that this situation may cause a disruption of Medicaid services to patients whose pharmacy has gone out of business due to reimbursement rates that are lower than acquisition costs.

A recent report by the Government Accounting Office (GAO) estimated that for the 77 multiple source drugs included in the study, the AMP based federal upper limits were on average 36 percent lower than the average retail pharmacy costs. While it was indicated in the regulatory impact analysis of the proposed rule that retail pharmacies would be able to make up the difference through sales of non-prescription drugs and other items, many pharmacies serving long-term care and other institutional settings are closed door pharmacies that do not sell prescription drugs or other items at retail to members of the general public.

Another concern we have is that AMP could become the standard by which other payers reimburse for pharmacy services. The proposed rule would require AMP listings to be published on the CMS web site, thus making them available to the general public. This could trigger private payers to begin reimbursing pharmacies at the AMP rate. As indicated earlier, retail pharmacies do not have access to price concessions given to mail order pharmacies and PBMs.

Dispensing fees

Compensation to pharmacies for dispensing a prescription includes reimbursement for the drug product and a dispensing fee. The combined total must be adequate to ensure ongoing financial viability of the pharmacy. If the pharmacy margin on product reimbursement is decreased, the dispensing fee must be increased by an equivalent amount to maintain the viability of the pharmacy.

ASCP agrees with CMS that dispensing fees may be higher with respect to a higher level of service provided to the patient. In fact, CMS recognized that in a March 15, 2005 guidance document that outlined ten service and performance criteria for long-term care pharmacy services under Medicare Part D. These services include 24-hour emergency services, delivery and specialized packaging. Results from a 2002 study that examined the cost of dispensing a prescription in long-term care estimate that it costs more than $11.00 (http://www.ltcpa.org/pdf/BDO.pdf). Additionally, long-term care pharmacies dispense IV medications which tend to be more costly than

non-IV medications. CMS should consider exempting IV medications from the AMP calculation. Further, ASCP recommends that CMS urge states to adopt higher dispensing fees for those pharmacies that provide additional services such as those outlined in the CMS long-term care pharmacy guidance.

According to a national study conducted by Grant Thornton LLP on behalf of the National Association of Chain Drug stores and the National Community Pharmacists Association, the national average cost of dispensing was $10.51 per prescription and $12.81 per pharmacy (http://www.ncpanet.org/pdf/codstudy-execsumm.pdf). The cost of dispensing per prescription combines low volume and high volume pharmacies. Typically, high volume pharmacies have a lower cost of dispensing than low volume pharmacies. Conversely, the cost of dispensing per pharmacy treats every pharmacy equally, regardless of prescription volume. The report concluded that cost per prescription is generally lower than cost per pharmacy since lower cost prescriptions make up a larger portion of the population when calculating cost per prescription. This study would suggest that dispensing fees must be high enough to accommodate lower volume pharmacies whose cost of dispensing appear to be higher than pharmacies that have a high volume of prescriptions.

For the reasons mentioned above, ASCP is respectfully requesting CMS to re-evaluate this new FUL based upon AMP and take into account national studies outlining the cost of dispensing, the unique nature of long-term care pharmacies, and the impact this proposed rule will likely have on rural, independent pharmacies. Additionally, we ask that CMS revise its calculation of AMP to exclude drugs purchased through mail order and PBMs. Thank you for the opportunity to provide comments on this proposed rule.

Sincerely,

Thomas R. Clark

Thomas R. Clark, RPh, MHS
Director, Policy and Advocacy

cc.
Senator Max Baucus
Senator Charles Grassley
Representative John Dingell
Representative Joe Barton

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February XX, 2007

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

Dear Ms. Norwalk,

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

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

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

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

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

Sincerely,

KAMRAN KHAN
SLEEPY HOLLOW PHARMACY Ste-D.
95-BEEKMAN AVE.
SLEEPY HOLLOW NY 10591
914-366-4000

88-2

Cottrill's Pharmacy, Inc.

Cottrill's Pharmacy, Inc.
255 Main Street
Arcade, New York 14009

Phone 585-492-2310

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Sincerely,

M J Adamiesj, Pres. RPh

February 16, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20,2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacies are located in Tell City and Rockport INDIANA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

For AMP definition to reflect market reality, PBM and mail order pharmacy purchases must be removed from the retail class of trade. We in retail pharmacy are prohibited from accessing PBM and mail order pricing both by the drug manufacturers and by laws which prohibit us from collective bargaining. Yet as the current definition is stated, we will be reimbursed at that rate. Absurd! This calculation represents the biggest threat to the existence of independent pharmacies in my lifetime. I believe both my stores will close within 1 year of implementation of AMP if left unchanged leaving a tremendously less competitive marketplace for consumers. The physicians in my area know where to check for the best cash pricing on prescriptions for their uninsured patients, not Walmart, not CVS, Werner Drug Store and Rockport Pharmacy.

Secondly, implement a trigger mechanism to address severe price fluctuation. This will reduce the risk that one player will gain disproportionately from market manipulation. It will also mitigate the risk of a pricing lag which could damage many pharmacies.

Last, use the 11 digit NDC number which is currently required for third party billing. To do otherwise is inaccurate and does not represent the most common package size dispensed by retail pharmacies.

In closing, I ask you to be aware of the catastrophic effect your current definition will have on the marketplace. If your goals are to eliminate small independent retail pharmacies from the marketplace, this definition will do it. If your goal, however, is to maintain a competitive dynamic marketplace where all consumers will benefit, don't strike down the David for a shortsighted dalliance with Goliath – implement the changes I have outlined.

Sincerely,

Brad N. Harth R.Ph. Werner Drug Store and Rockport Pharmacy

1134 Washington St.
Tell City, IN 47586