CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

February 16, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: (CMS-2238-P) Medicaid Program: Prescription Drugs, Proposed Rule, (Vo. 71, N0. 246), December 22, 2006

Dear Ms. Norwalk:

The California Hospital Association (CHA), on behalf of our 450 member hospitals and health systems, is pleased to provide comments on the proposed rule implementing the Medicaid prescription drug program provisions of the *Deficit Reduction Act of 2005* (DRA). Our comments address CMS' interpretation of Section 6002 of the DRA and the new requirement that all outpatient settings, including hospitals, report physician-administered drugs using the National Drug Code (NDC).

Our comments focus on the following issues:

- the legal premise upon which CMS has based its interpretation of Section 6002,
- the significant administrative burden – and the associated costs – these new reporting requirements impose on hospitals, and
- the potential impact to safety-net hospitals if they are no longer able to participate in the 340B drug program.

Conditions Relating to Physician-Administered Drugs – Section 447.520

Section 6002 of the DRA added a new requirement to the Medicaid statute specifically to enhance the ability of state Medicaid (Medi-Cal in California) programs to secure rebates from drug manufacturers under the Medicaid drug rebate law. This section ties Medicaid rebate payments for covered outpatient drugs that are physician administered, as determined by the Secretary, to "the collection and submission of such utilization and coding data (such as J-codes and NDC numbers) ....as necessary to identify the manufacturer of the drug." The data collection requirement extends to both single and multiple source drugs.

However, in the proposed rule, CMS does not define "outpatient drugs that are physician administered" as the statute clearly states that the Secretary must do. Instead, the rule's preamble indicates that CMS intends to interpret Section 6002 to require submission of the NDC numbers for outpatient drugs furnished as part of a physician's service to Medicaid beneficiaries in hospital outpatient clinics and departments – not solely in physicians' offices. CMS' proposal to apply Section 6002 so broadly is incorrect. It is not supported by the statute's plain language, is inconsistent with congressional intent, and would nullify the *Social Security Act of 1965*

exemption of hospital outpatient clinics and departments from Medicaid rebate program obligations.

Section 6002 requires only the collection of utilization and coding data for drugs that are subject to a rebate requirement under Medicaid statute provisions that predate the DRA. Under Section 6002, state Medicaid programs are expressly directed to provide for the submission and collection of drug utilization and coding data "as necessary to identify [manufacturers of drugs] in order to secure rebates" under the Medicaid rebate law. For outpatient drugs that are not subject to a rebate payment requirement – like those dispensed in hospital outpatient clinics and departments – the collection of NDC information with respect to that drug plainly is not necessary to securing a rebate, and the law does not require submission or collection of NDC data on the drug.

The statutory language, in fact, does not directly compel states to collect only NDC information on drugs subject to the rebate requirement. While reporting of the NDC numbers is preferred after January 1, 2007, the statute clearly authorizes the Secretary to allow for an alternative coding system. The statute states that the purpose of the data collection is "as necessary to identify" the manufacturer of the drug in order to collect Medicaid manufacturer rebates. The statute mentions J-codes and NDC numbers as examples of the type of "utilization and coding data" that could be collected. To the extent that J-codes can be used to identify a drug for Medicaid rebate purposes, use of J-codes to identify drugs is consistent with statutory compliance.

Section 6002 does not affect the existing rebate exemption for drugs administered to patients in hospital outpatient clinics and departments

Nothing in Section 6002 casts doubt on the continuing existence of the Medicaid statute's pre-existing exemption from drug rebate requirements for outpatient drugs established by Section 1927(j) of the *Social Security Act*. Section 6002's language is entirely silent as to any legislative intent to repeal or amend this pre-existing exemption, which expressly identifies outpatient drugs dispensed through hospital outpatient clinics and departments as not subject to the Medicaid drug rebate requirements.

The DRA Conference Report explicitly states that hospital outpatient clinic and managed care drugs described in Section 1927(j) are exempt from rebate requirements, and that the Section 6002 data collection requirements are intended to pertain only to physician-administered drugs for which there is no statutory exemption from rebate requirements (See H.R. Rept. No. 109-362 accompanying S.1932, December 19, 2005) Although the conference report does not directly cite Section 1927(j) *per se*, it expressly acknowledges the existence of exemptions from rebate requirements for outpatient prescription drugs using terms that unmistakably mirror the descriptions of managed care drugs in Section 1927(j)(1) and hospital drugs in Section 1927(j)(2).

It is clear that the physician-administered drug provision enacted by Section 6002 can only be read to impose a data collection requirement with respect to drugs that are not within the Section 1927(j) (2) exemption. Because the subsection (j) remains unchanged in the Medicaid rebate law, CMS cannot ignore the statutory exemption. The agency must continue to give subsection (j) the same meaning it had prior to the enactment of the DRA as the agency applies Section

6002. In doing so, CMS is compelled to draw meaning from Section 1927(j) (2) in a concrete way by referring to drugs dispensed or administered in an actual hospital setting.

Section 1927(j)(2) specifically exempts from the rebate requirements outpatient drugs that are administered in a "hospital ... that dispenses covered outpatient drugs using formulary systems, and bills [the Medicaid State Plan in the relevant state] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan)." This section cannot plausibly be construed as a reference to hospitals participating in the 340B federal drug discount program because the 340B program did not exist at the time Section 1927(j) was enacted.

On the other hand, drugs administered by medical professionals to patients on an outpatient basis in hospital clinics and departments generally have not been subject to Medicaid rebate collections, and fall squarely within the (j)(2) exemption, as properly construed. Drugs administered in the hospital outpatient clinic setting are dispensed almost always within a formulary system – thus meeting the first statutory criterion for inclusion in the (j)(2) exemption. Covered outpatient drugs administered in hospital clinic settings also are billed to Medicaid in a manner that meets the description of the second (j)(2) criterion, namely that the hospital "bills the [Medicaid State Plan] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the state plan)." Most, if not all, drugs administered to Medicaid-eligible patients in hospital outpatient clinics and departments fall within the (j)(2) exemption from rebates, and accordingly must be excluded from the physician-administered drugs to which Section 6002 applies.

Administrative and Financial Burden for California Hospitals

California is moving forward with implementing this new NDC reporting requirement with planned implementation January 1, 2008. CHA is concerned because these instructions fail to recognize the significant difficulty, burden and cost imposed upon California's hospitals in order to meet these new billing requirements. Hospital patient accounting systems are not designed to handle the routine reporting of a drug manufacturer's NDC. Today, hospital patient accounting systems rely on the Healthcare Common Procedure Coding System (HCPCS) to report a particular drug or biologic rendered to a patient.

It should be noted that the language in the DRA conference report specifically indicates that the state Medicaid programs must "provide for the collection and submission of utilization and coding information for each Medicaid multiple source drug that is physician administered." The DRA further states that the "reporting would include J–codes and NDCs." As such, CHA believes that state Medicaid agencies must provide for the collection process and bear the cost for hospitals to meet these new NDC reporting requirements. State Medicaid programs should pay hospitals to handle the system changes and new work routines required to collect and submit this coding information. California estimates rebates will net the state Medicaid program approximately $50 million. Hospitals will clearly be required to invest this much and more to ensure compliance with this onerous rule.

Preliminary estimates, which focus on rudimentary changes to hospital systems, indicate that it will take roughly 500 to 1,500 work hours to design, build and test a short-term work around. Early estimates are that California hospitals could be required to spend $1 million and more to make the necessary system and staffing changes to put these reporting requirements in place. It

is worth noting that California's Medicaid expenditures per beneficiary are either the lowest in the nation or among the lowest (depending on which data source cited). Requiring such an expensive, onerous requirement with no hope of recovering any of the associated costs will force hospitals to cut costs in other areas. This could result in hospitals reducing services and compromised access to care for all Californians.

When a drug needs to be replenished, the pharmacy goes to the primary manufacturer; however, often the primary manufacturer cannot supply or meet the hospital's need. In such instances, the hospital pharmacy seeks a secondary drug from another manufacturer with a different NDC. Therefore, the hospital pharmacy record keeping systems will need the ability to include multiple secondary sources for similar drugs. These changes also require massive system modifications and additional work routines.

During the past several years many hospitals have introduced new automated drug dispensing systems in an effort to reduce medication errors. Many of these systems also would require costly modifications. For example, these drug dispensing systems have bins for each specific drug based on ingredient and dosage – not on manufacturer NDC. There also is a human cost since hospitals that are interested in acquiring such systems to reduce medication errors would have to postpone their acquisition until the vendors make all of the system modifications. And, patient safety could be compromised in other ways as hospitals transition to using and reporting NDC.

This proposed rule applies to Medicaid only. This eliminates efficiencies and administrative simplification – and increases costs – that comes with submitting standard claims using standard coding systems. The bottom line is this proposed requirement requires a costly upgrade without tangible benefit for Medi-Cal patients.

340B Prescription Discount Program for Safety-Net Hospitals

California's safety-net hospitals are concerned about the potential impact on the "340B Program." Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to provide discounts on covered outpatient drugs purchased by specified entities – including safety-net hospitals. Hospitals participating in the 340B Program are entitled to receive 340B discounts on all covered outpatient drugs. One condition of participation is that a drug purchased under Section 340B shall not be subject to both a 340B discount and a Medicaid rebate. To avoid these duplicate discounts, 340B hospitals bill Medi-Cal at acquisition cost (plus dispensing fee) for 340B drugs, and Medi-Cal, in turn does not collect manufacturer rebates on the drugs acquired at the discounted 340B prices.

If Medi-Cal collected rebates on drugs administered to Medi-Cal patients in hospital outpatient settings, this would result in manufacturers providing duplicate discounts on many of those drugs because manufacturers already will have provided the 340B discounts to participating hospitals.

If Medi-Cal were to pursue rebates as planned – which ultimately would entail the 340B hospitals essentially passing their 340B savings on to California instead of using them to stretch their own indigent-care resources – it likely would drive many 340B providers out of the program. Ultimately this would increase Medi-Cal net drug costs by depriving Medi-Cal of the savings it now derives from these hospitals' participation in the 340B Program. The fiscal

LOUISIANA INDEPENDENT PHARMACIES ASSOCIATION

BY OVERNIGHT DELIVERY FOR
NEXT BUSINESS DAY PRIORITY DELIVERY

February 17, 2007

Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attn: CMS 2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: File Code CMS-2238-P
Comments in Response to Notice of Proposed Rule (December 22, 2006)

These comments are offered on behalf of the Louisiana Independent Pharmacies Association in response to the Notice of Proposed Rule published by the Centers for Medicare and Medicaid Services (CMS) in the federal register on December 22, 2006 (File Code CMS-2238-P). The Louisiana Independent Pharmacies Association (LIPA) has approximately 270 members, which are licensed by the State of Louisiana. Many LIPA members serve rural areas, and all LIPA members serve a large Medicaid beneficiary population. In some areas of Louisiana, an independent pharmacy is the only pharmacy available to serve the Medicaid population.

The LIPA first takes this opportunity to discuss the prescription drug distribution systems and related transactions, including the various "players" that are involved in different aspects of the system. There are numerous parties and transactions involved in getting a prescription drug from a manufacturer and into a patient's hands. Understanding how these many parties do business and the nature of their transactions is important to how CMS decides to define AMP. Developing a methodology that results in reimbursement rates sufficient to protect beneficiary access to prescription drugs and pharmacy counseling and education services should be CMS's goal.

Drug manufacturers have relationships with numerous other entities. Not all of their relationships involve the sale by the manufacturers to an entity such that the entity takes delivery and then redistributes the drug to a retail pharmacy. Some manufacturer relationships involve significant price concessions that do not encompass the distribution of drugs. Moreover, these price concessions are not enjoyed by independent pharmacies.

Manufacturers sell some prescription drugs to wholesalers, which are entities that take delivery of the drugs and redistribute them "down the line" in the distribution chain. Wholesalers take delivery and provide inventory management services, for which they receive management fees. Wholesalers distribute prescription drugs to independent pharmacies, as well as to other entities. There is no requirement that wholesalers who purchase drugs and re-sell them to pharmacies must pass manufacturer price concessions on to retail pharmacies. Generally, they do not do so. Independent pharmacies receive very little, if any, manufacturer price concessions.

Manufacturers also have relationships with pharmacy benefit managers (PBMs). PBMs manage the pharmacy benefit portion of third party payer plans such as managed care plans. PBMs do not purchase and take delivery of drugs for re-sale as wholesalers do. PBMs negotiate with manufacturers for the sale by the manufacturers of prescription drugs to mail order pharmacies. Often, these mail order pharmacies are related parties to the PBM.

Again, PBMs do not purchase drugs. The primary function of PBMs is to manage the pharmacy benefits of managed care plans and employer-sponsored health plans (ERISA plans). PBMs process claims and develop drug formularies. As plan managers, their establishment of formularies means they decide (or

recommend for decision) which drugs the plan will cover. This decision is very important to manufacturers because a very large number of insured lives are covered by these plans. Therefore, manufacturers pay substantial rebates to PBMs to have their drugs placed on the managed care plan formulary. Just as manufacturers pay rebates to States for their drugs to be covered by the State's Medicaid Program, they pay rebates to have their drugs on managed care plan formularies. PBMs also receive other payments and/or price concessions from manufacturers. It is a matter of contract between a PBM and a managed care plan as to how much these rebates and/or other price concessions are passed on to the managed care plan. In any event, **no** price concessions are passed on to independent pharmacies that participate as network providers in these plans.

Because of the manufacturer-PBM relationships, mail order pharmacies that are related to PBMs are able to obtain price concessions on drugs purchased by the mail order pharmacies. Mail order pharmacies also have the opportunity to increase business because PBMs through plan management have the ability to direct patients to mail order pharmacies. For example, some plans require the use of mail order for maintenance drugs after a certain number of refills at the retail pharmacy.

Exactly what portion of PBM-negotiated price concessions is kept and what portion is passed on is not clear, because they take the position that certain financial PBM data is proprietary. In any event, independent pharmacies do not participate in any of these price concessions.

Independent pharmacies do not have the negotiating power of PBMs. Nor do they have the purchasing power of a wholesaler.

PBMs also negotiate managed care plan, ERISA plan and Medicare Part D plan network arrangements with independent pharmacies. These contracts are PBM-created and are "take it or leave it" agreements in virtually all instances. These agreements control prescription drug reimbursement under the plans, for both ingredient cost reimbursement and dispensing fee reimbursement. Dispensing fee reimbursement **is not** calculated on the basis of covering all costs associated with dispensing a drug.

Just as PBMs do not generate any price concessions for community pharmacy, neither do the Medicaid Program or the Medicare Program. No third party payer plan, whether government or private, generates any price concessions for independent pharmacies. However, all efforts to this point to control cost, whether publicly or privately induced, have fallen almost entirely upon community pharmacies.

In summary, independent pharmacies do not enjoy, and do not have the power to enjoy, price concessions such as those PBMs, mail order pharmacies and wholesalers enjoy. Moreover, none of the price concessions that PBMs enjoy are passed on to community pharmacies. In other words, community pharmacies pay more for their drugs. Additionally, community pharmacies fill and dispense prescriptions at costs well above the dispensing fee reimbursement rates they receive. Accordingly, independent pharmacies are the least likely to be able to absorb and make up for decreases in Medicaid ingredient reimbursement. Community pharmacies fill the majority of Medicaid prescriptions, and many community pharmacies provide prescription drugs and valuable face-to-face counseling as the only pharmacy provider in rural areas. They offer services such as quick delivery and drug education to a most vulnerable population. This population needs continued access to community pharmacy.

The GAO has recently identified the potential for significant reimbursement shortfalls resulting from the current reporting of AMP to determine reimbursement rates. The changes in Medicaid prescription drug reimbursement under the Deficit Reduction Act of 2005 (the DRA) will have a large impact on the financial viability of independent pharmacies, not only in Louisiana, but also nationally. It is important to all independent pharmacies, and to the various Medicaid Programs throughout the nation, that beneficiary access be maintained. The loss of even one (1) independent pharmacy can negatively impact beneficiary access to prescription drugs, as well as to vital face-to-face counseling and education beneficiaries receives. Without this personal service, health would be seriously impacted, hospital admissions would increase, and the economy would be negatively affected. CMS must carefully consider the ramifications of the determination of AMP going forward. CMS should develop a determination that does not artificially deflate AMP by including price concessions from selective transactions, i.e. transactions in which some parties (community pharmacies) in the delivery systems are not allowed to participate. How CMS determines AMP, and whether CMS is careful to act within the authority delegated by Congress, in the DRA and otherwise, is crucial to independent pharmacies. The LIPA's comments are offered in the spirit in protecting this vital healthcare provider-patient relationship to the benefit of the healthcare delivery system and the very vulnerable Medicaid population.

Comments on Proposed Definitions

Dispensing Fee.

The LIPA commends CMS for defining the phrase "dispensing fee" in an attempt to provide guidance to States for making the important determination of a fair and reasonable level of reimbursement for the dispensing fee portion of Medicaid prescription drugs. The LIPA also thanks CMS for making clear that there is only one (1) determinant for calculating dispensing fee reimbursement-costs. The LIPA respectfully asks CMS to provide further clarification of the definition to insure that for whatever formula states may use for determining dispensing fee reimbursement, any such formula covers all costs associated with providing drugs and services to Medicaid beneficiaries, including all costs necessary to operate the pharmacy. For example, the LIPA believes that CMS should clarify that such costs are not limited to those that occur "behind the counter." Not all costs associated with filling prescriptions and operating a pharmacy occur behind the counter. All costs, overhead and otherwise, associated with pharmacy operations should be taken into account. Additionally, the LIPA asks CMS to instruct that dispensing fees should be based on current costs or, alternatively, should be adjusted for inflation on a regular basis. The LIPA asks CMS to make clear that a "reasonable dispensing fee" under federal regulations is one that covers all appropriate costs, as well as a reasonable return on investment.

Wholesaler.

CMS does not include the word "wholesaler" in the Definition section of the commentary to the Proposed Rule. However, in the text of the Proposed Regulations themselves, CMS defines "wholesaler" in proposed Section 447.504(f) as "any entity (including a pharmacy, chain of pharmacies, **or PBM**) to which the manufacturer sells, **or arranges for the sale of**, the covered out-patient drugs, but that does not relabel or repackage the covered out-patient drug" (emphasis added). The LIPA respectfully submits that this definition should not be adopted in the Final Rule. The LIPA submits that the phrases shown above in bold should be deleted, for several reasons.

First, the proposed definition is contrary to how the term "wholesaler" is defined in the National Rebate Agreement. There, the term "wholesaler" means "any entity (including a pharmacy or chain of pharmacies) to which the labeler **sells** the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug" (emphasis added). A wholesaler purchases, takes delivery and redistributes drugs to retail and institutional pharmacies. Releases 28 and 29 confirm that PBMs do not automatically meet this definition. They state that drug prices to a PBM affect best price calculations but do not affect AMP calculations **unless** the PBM is acting as a wholesaler as defined in the rebate agreement. PBMs do not purchase, take physical delivery or redistribute drugs to the point of sale.

Second, the term Average Wholesale Price (AWP), which has been the basis for determining brand name drug reimbursement under Medicaid, is instructive. In September, 2001, Thomas A. Scully, who at the time was the Administrator of CMS, testified before Congress that AWP is intended to represent the average price at which "wholesalers sell drugs to their customers." This testimony can be found at the joint hearing before the Subcommittee on Health and the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, 107th Congress. 87-88 (2001). Additionally, in the 2003 Medicare Prescription Drug and Improvement and Modernization Act, in H.R. Rep. No. 108-178, Part 2, at p.194, Congress noted that AWP was intended to represent the average price at which wholesalers sell prescription drugs to their customers. Wholesalers are parties in the chain of distribution and delivery. PBMs do not meet these criteria.

Third, in 42 U.S.C. § 1396 r-8(b) (3) (B), in referencing the terms of the National Rebate Agreement, Congress refers to the direct distribution of covered outpatient drugs by wholesalers and manufacturers. In other words, Congress recognizes that wholesalers are drug distributors.

Fourth, PBM transactions, and, therefore, any price concessions PBMs obtain for themselves or for others, should not be considered manufacturer-wholesaler transactions, because, as stated at the beginning of these comments, **no price concessions obtained by PBMs are passed on to independent pharmacies**. To include PBMs in the definition of wholesalers would permit the inclusion of price concessions to **which independent pharmacies do not have access**. For these reasons, PBMs should not be characterized as wholesalers.

Comments on Retail Pharmacy Class of Trade and the Determination of AMP

The LIPA first notes that the definition of Average Manufacturer Price (AMP) is statutory. It was defined by Congress many years ago and has been amended slightly by the DRA, but only to exclude prompt payment discounts extended to wholesalers from the calculation of AMP. Congress has defined AMP as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, [excluding customary prompt pay discounts extended to wholesalers]." Clearly, the only transactions to be included in determining AMP are those that: (1) are prices paid by wholesalers to manufacturers; and (2) apply to the purchase of prescription drugs by wholesalers from manufacturers for the wholesalers' redistribution to the retail pharmacy class of trade. The definition of "retail pharmacy class of trade" is relevant to the determination of AMP to the extent that wholesalers must know (and report) which of their purchases, and attendant prices, apply to drugs that they redistribute to this class. However, the prices paid by the retail pharmacy class of trade (and, for that matter, by those non-wholesaler entities that do not fall within the retail pharmacy class of trade) to the wholesaler are not determinative of AMP.

In determining the price paid by the wholesaler to the manufacturer, only rebates, discounts, fees (other than bona fide service fees) and other price concessions between the manufacturer and wholesaler are appropriate for deduction from the reportable price. Any other manufacturer price concession (whether made to a PBM, hospital, nursing home, retailer pharmacy or other entity) should not be included in a determination of AMP. This is because the definition is statutorily limited to prices between manufacturers and wholesalers, and for only certain transactions between them. Congress has specifically excepted prompt pay discounts between the manufacturer and the wholesaler from the definition, making it reasonable to conclude that only price concessions **between manufacturers and wholesalers** should be included in the definition. However, any expansion of the determination of AMP to transactions beyond the manufacturer-wholesaler relationship, and/or to transactions by manufacturers to other than the retail pharmacy class of trade is beyond the intent and delegation of Congress.

Moreover, as explained earlier, extending the definition of wholesaler to include PBMs (or any other non-wholesaler) would be contrary to the intent of Congress, and contrary to the National Rebate Agreement.

For these same reasons, mail order purchases, Medicaid or SCHIP payments, or Medicaid Part D payments should not be included in the determination of AMP. None of these entities or Programs is a wholesaler; therefore, none of their payments should be included in the calculation of AMP. Additionally, none of them should be included in the definition of the retail pharmacy class of trade, for the reasons that follow.

First, mail order pharmacies purchase their drugs directly from manufacturers (often via PBM negotiations on behalf of the mail-order pharmacies). Accordingly, their transactions would not yield a manufacturer-wholesaler transaction. Without that relationship, their transactions should not be included in a determination of AMP.

Second, mail order pharmacies do not provide face-to-face healthcare to prescription drug recipients. They do not incur the same level of costs and overhead that traditional retail (chain and independent) pharmacies incur. Because they enjoy lower costs of dispensing than retail pharmacies, they stand to benefit disproportionately from dispensing fee increases under Medicaid based on the average cost to dispense. This average cost determination will be made, for the most part, from the survey of costs incurred by traditional chain and independent pharmacies, which make up the overwhelming majority of dispensing fee survey participants in a State.

Third, mail order pharmacies are usually located in lower-rent warehouse districts. The also do not face the higher costs that brick and mortar pharmacies incur to maintain OSHA and ADA compliance.

Fourth, as stated earlier, mail-order purchases often are negotiated by PBMs at prices that traditional retail pharmacies, especially independent pharmacies, cannot achieve. Accordingly, in light of the potential for the above-stated dispensing fee benefit and the benefit of price concessions unavailable to traditional pharmacies, including mail-order pharmacies in the retail pharmacy class of trade would lead to a further artificial deflation of AMP.

Fifth, CMS should define the retail pharmacy class of trade as those pharmacies that provide face-to-face service to patients, offer timely delivery, can provide 24/7 availability and response to patient needs, and are available to patients in the event of a disaster. Independent pharmacies were available and played a major roll in providing vital

drugs and services in the aftermath of Hurricanes Katrina and Rita. They often did so without knowing whether they would be compensated.

Finally, the LIPA submits that hospitals and nursing home pharmacies do not distribute drugs to the general public. This is true for both hospital inpatient and out-patient pharmacy business. Accordingly, they should not be included in the retail pharmacy class of trade.

In summary, there are strong policy reasons for including in the retail pharmacy class of trade only those traditional retail pharmacies (chains and independents) that provide face-to-face healthcare to their patients, including Medicaid beneficiaries.

Comments on Manufacturer Requirements

The LIPA submits that retail pharmacies, and independents in particular, need certainty and reimbursement based on the least amount of erratic price reporting possible. In the Notice of Proposed Rule, CMS' proposed Section 447.510 addresses monthly reporting of AMP, from which FUL reimbursement will be calculated. Section 447.510 permits reporting of monthly AMP up to thirty (30) days after the month for which it is reported. CMS contemplates permitting manufacturers to report monthly AMP based on estimates of end-of-the-quarter rebates and other price concessions. As stated earlier, these concessions should be limited to those between manufacturers and true wholesalers.

The LIPA questions whether this 30-day allowance will result in FUL reimbursement at levels that will be up to thirty (30) days old. The LIPA also questions why monthly AMP should have such a long adjustment period when quarterly rebates and price concessions cannot change monthly AMP that is more than 30 days old. For some months in a quarter, adjustments would be irrelevant, because they would occur beyond the 30-day adjustment period. Accordingly, the LIPA suggests that CMS consider modifying its proposed rule regarding the 30-day period and applying a different adjustment period analysis that addresses these issues.

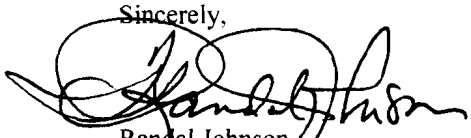
Retail pharmacies are notified electronically at the point and time of sale what their reimbursement will be for a particular prescription drug. Under the DRA, States will be required to reimburse for prescription drugs to which a federal upper limit applies, in the aggregate, at no greater than 250% of AMP. Pharmacies need certainty and fairness and should be entitled to reimbursement at the then-current AMP. Accordingly, the LIPA also requests that, in addition to reconsidering a reduction in the 30-day period, CMS require reasonable reporting of estimates and assertively enforce the prohibition against adjusting monthly AMP beyond whatever period is chosen in lieu of the 30-day period. Including only true manufacturer-wholesaler transactions, as well as a narrowly tailored monthly AMP reporting period should result in easier, less varied (and, therefore, more uniform and more reliable) manufacturer determinations.

Summary/Conclusion

Community pharmacy must continue to thrive and survive in order for beneficiary access not to be negatively affected. In its preamble to the Notice of Proposed Rule, CMS suggests that the effect of the Proposed Rule will be a reduction in retail prescription drug revenues by less than one (1%) percent, on average. CMS assumes that actual revenue losses would be even smaller because, "almost all of these stores sell goods other than prescription drugs" and "overall sales average more than twice as much as prescription drug sales." The proposed rule also assumes pharmacies have the ability to mitigate the effects of the rule by simply changing purchasing practices. The LIPA respectfully disagrees. As CMS is aware, the Government Accountability Office has recently issued a report after studying seventy-seven (77) generic drugs and has determined that, on average, FUL as proposed under the DRA will be thirty-six (36%) below the pharmacy's actual acquisition cost. Additionally, the LIPA questions why CMS believes that independent pharmacies can cover the FUL-estimated losses by simply changing purchasing patterns. If this were the case for independents, then there would be no good reason for independents not to have already made these changes, with or without the DRA. Finally, the LIPA asks CMS to reconsider whether, at least in the case of independent pharmacies, the sale of items other than prescription drugs makes up a large, or even an appreciable, percentage of total sales. The answer is they do not. The bottom line for community pharmacy is as CMS notes: the Proposed Rule is likely to have a "significant impact" on some pharmacies.

The LIPA also asks CMS to consider whether community pharmacies are the entities most capable of absorbing the negative financial effects of reduced reimbursement under the DRA. CMS states in its Notice of Proposed Rule that it is unable to estimate specifically what the impact will be on small retail pharmacies, particularly those in low income areas. The LIPA suggests that this fact, in and of its self, should be a sufficient reason to develop a definition of AMP and the retail pharmacy class of trade that protect access. The impact on access will be multiplied in those instances where the costs associated with filling Medicaid prescriptions and operating the pharmacy is currently twice or more than current average dispensing fee reimbursement. The LIPA asks CMS to give its comments serious consideration and to move cautiously in developing the Final Rule. Beneficiary access is what is at stake.

Sincerely,



Randal Johnson
President & CEO
Louisiana Independent Pharmacies Association

AstraZeneca

February 20, 2007

By Courier

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Centers for Medicare & Medicaid Services
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Washington, D.C. 20201

Re: CMS-2238-P

Dear Ms. Norwalk:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP) ("AstraZeneca") is pleased to submit the following comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled, "Medicaid Program; Prescription Drugs," published on December 22, 2006.

AstraZeneca is a leading global healthcare company dedicated to the research and development of new medicines in therapeutic areas including cardiovascular, gastrointestinal, oncology, respiratory, and neuroscience. AstraZeneca is committed to the discovery of drugs that will allow patients to lead longer, healthier and more productive lives. We conduct and support scientifically robust research that improves the delivery of effective, high-quality care to patients.

AstraZeneca is pleased that CMS issued such a detailed proposed rule for purposes of implementing many of the Medicaid provisions contained within the Deficit Reduction Act (DRA). A clear definition of Average Manufacturer Price (AMP) as well as other terms utilized within the Medicaid rebate program will assist manufacturers in making accurate submissions to CMS. In addition, AstraZeneca commends CMS for its effort in ensuring AMP is correctly defined before it is used directly for Medicaid reimbursement purposes. It is with the purpose of both clarifying the definition of AMP and other associated terms, and protecting patient access to medications under the Medicaid program that we submit our comments to CMS.

AstraZeneca believes it is critical that the Medicaid program protect patient access to medications and provider access. Accordingly, we recommend that CMS consider the following recommendations when finalizing the rule:

- CMS should provide sufficient clarity in regard to the definition of AMP so as to remove ambiguity and/or the potential for variation in interpretation across manufacturers.

- CMS should commit to updating the Medicaid regulations and/or guidance on a regular basis so that manufacturers have clear guidance in regard to the treatment of new and evolving classes of trade within the retail channel. Such regular updating will prevent the current situation where significant ambiguity of the AMP definition resulted in different practices across manufacturers.

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- It should be clearly noted in the final rule that the changes to the definition of AMP as well as other proposed regulations pertaining to the Medicaid rebate program are prospective in nature. As such, manufacturers will comply with all changes once the rule is finalized, but the government will not penalize manufacturers for practices that may have differed prior to the finalization of the changes.

- AMP data should not be publicly available until such time as all manufacturers have made consistent submissions using the finalized calculations. To publish AMP values before such time would cause market confusion, as different methodologies may still be in place across manufacturers.

- Given that AMP is likely to be used as the index for setting Medicaid reimbursement rates, CMS should carefully evaluate the reimbursement rates developed by states to ensure that the new rates, including dispensing fees, approximate actual pharmacy costs. Without this systematic review, CMS and the states may jeopardize patient access to essential medications covered under the Medicaid program.

The recommendations are discussed in detail in the following pages. For your convenience, our comments reference the particular portions of the proposed rule to which they apply.

AstraZeneca thanks you for the opportunity to comment on this important proposed regulation, and we look forward to continued collaboration.

Sincerely,

Christine McHenry

Christine McHenry
Director, Government Operations

Cc: Mr. Larry Kocot
Senior Advisor to the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

COMMENTS BY SECTION

Section 447.502: Definition of Bundled Sale

AstraZeneca recognizes that CMS saw the importance in offering more specific guidance in regard to allocating discounts associated with bundled contracts. While we appreciate this position, we believe that the new definition has inadvertently caused confusion regarding what constitutes a bundled arrangement. For example, it could be assumed that any type of comprehensive, multi-product, portfolio contract could fit within CMS' proposed new definition. We do not believe that this was CMS' intention; nor do we believe such a result would be appropriate. Therefore, we ask CMS to: (1) provide examples of bundled discounts that meet whatever definition is finalized, and (2) explicitly clarify how discounts meeting the bundled discount definition should be allocated across products.

Section 447.504: Definition of Retail Pharmacy Class of Trade and Determination of AMP

Overarching Comments:
AstraZeneca commends CMS for using the proposed rule to define explicitly the retail class of trade. We agree that such clear guidance is needed so that manufacturers can determine if their business practices comply with the definition. As CMS recognizes, the definition of the retail class of trade is very complex and nuanced, requiring a very granular definition for manufacturers to update their systems and operations accordingly. As such, we believe that there are areas within the proposed rule that require further specification from CMS. The areas necessitating more clarification are delineated below.

Specific Comments:

Pharmacy Benefit Manager (PBM) Price Concessions
As CMS recognizes in the proposed rule, the business relationships among manufacturers, PBMs, and managed care organizations are very complex, and the terms of such relationships can vary across manufacturers and across particular products. We agree in concept with CMS that PBM rebates and discounts should be included in AMP, given that the associated prescriptions are primarily dispensed through the retail channel or via mail order. This concept should apply equally to include rebates paid by manufacturers under contracts directly with health plans except for staff model HMOs. In addition, as CMS notes, it is difficult if not impossible for many manufacturers to disaggregate PBM terms. Therefore, we believe that in the final rule CMS should be more directive and specific as to what types of PBM rebates and discounts should be included in AMP and how such terms should be stratified when calculating AMP. Perhaps the most practical and consistent approach would be one that simply states that all PBM rebates and discounts as well as those to health plans as described above should be included in AMP (i.e., used to reduce AMP sales in the numerator of the AMP calculation). In fact, without such specificity, the ambiguity that CMS is attempting to eliminate would remain in place, as individual manufacturers would adopt their own operating standards and assumptions.

State Pharmaceutical Assistance Programs (SPAPs)
We appreciate CMS' specific guidance regarding the treatment of discounts/rebates to SPAPs. However, we respectfully disagree with CMS' proposal to include discounts/rebates to SPAPs in AMP. Despite CMS' assertions as to why these discounts/rebates should be included in AMP, SPAPs are still government run programs, and discounts offered to SPAPs are often statutorily driven or otherwise not determined by market factors. In fact, the discounts/rebates offered to SPAPs are often the same as those offered to state Medicaid programs, per state requirements. Therefore, given that Medicaid rebates are excluded from AMP, we believe that the same logic should apply to SPAPs. In finalizing the AMP rule, we urge CMS to clarify that discounts/rebates offered to SPAPs are not included in the calculation of AMP.

Manufacturer Coupons
AstraZeneca is concerned that CMS' proposed definition is too narrow in terms of the treatment of manufacturer coupons when calculating AMP and Best Price. While we agree with CMS that coupon programs involving transactions between the patient and manufacturer should be excluded from AMP and Best Price, we believe that there are other similar programs that should also be excluded from AMP and Best Price. For example, patient programs can be adjudicated through a coupon presented to a pharmacist, or through a vendor who administers the coupon program, rather than by sending a coupon via mail to the manufacturer. Such programs are, for all intents and purposes, the same as traditional coupon programs in that these programs do not affect the price realized by the pharmacist. Since consumers are not included in the definition of AMP or Best Price (by statute or otherwise), and coupons do not affect prices paid by wholesalers or retailers, these types of programs should not be included in AMP or Best Price. Thus, we ask CMS to provide in the final rule that any type of consumer program, be it a patient assistance, coupon, or debit card program, be exempted from AMP and Best Price so long as such program does not affect the price paid by the pharmacist to acquire the product.

Such a clarification is vital in ensuring that manufacturers are able to continue to offer programs that result in lower drug prices to patients. Without such a clarification, manufacturers would be required to include certain types of these programs in their AMP and Best Price calculations.

Therefore we ask CMS to clarify that to the extent that the full amount of the discount goes to the consumer and does not affect the price realized by the pharmacist, or any end user other than a patient, such programs should be excluded from AMP and Best Price.

Specialty Pharmacy
AstraZeneca appreciates CMS' interest in using the proposed rule to provide guidance on those channels within the retail class of trade that have developed and evolved since the inception of the Medicaid rebate program. One such segment is the specialty pharmacy channel, a new and rapidly expanding channel where the goal is to provide patients with efficient and timely access to vital medications. Given that CMS' goal is to provide guidance on developing channels, we ask that CMS include specific guidance as to how discounts/rebates to the specialty pharmacy channel should be treated when calculating AMP. Clear guidance in the final rule would ensure that manufacturers consistently address the specialty pharmacy channel when calculating AMP.

Section 447.506: Authorized Generic Drugs

AstraZeneca recognizes that the DRA changed the AMP and Best Price reporting requirements for authorized generics. As this is a change to the statute, we recognize that CMS has limited flexibility in implementing the provision. However, we request that CMS provide additional operational guidance in the final rule in regard to how the blending of AMP and Best Price submissions for authorized generics should occur. In addition, we believe that there are a number of transactions that may not have been intended to fall within the scope of this provision, for example, contract manufacturing, original equipment manufacturing, and divested product transactions. Therefore, CMS should narrowly define the circumstances in which the authorized generic provisions apply.

Section 447.510: Requirements for Manufacturers

Baseline AMP

We commend CMS for providing manufacturers with the option to recalculate baseline AMPs. While we agree with this provision in concept, we ask CMS to provide additional clarification in three specific areas.

First, we ask CMS to specify whether manufacturers must make a decision to recalculate AMPs for their entire portfolio, or whether they can choose to do so on a product-by-product basis. As CMS notes in the proposed rule, the ability to recalculate baseline AMPs is dependent upon the availability of data. Therefore, manufacturers may be able to recalculate baseline AMPs for some products but not others.

Secondly, we request that CMS allow manufacturers to recalculate baseline AMPs even in situations where full historical data may not be available. In such situations, manufacturers should be authorized to utilize reasonable assumptions and consistent estimation methodologies. Manufacturers would provide CMS with the assumptions used in calculating baseline AMPs via any such alternate methodologies.

Third, we ask that CMS provide additional time for manufacturers to recalculate baseline AMPs. In the proposed rule, CMS requests that manufacturers submit the new baseline AMP information within one quarter of the publication of the final rule. We believe that it will not be possible for all manufacturers to complete the calculation within one quarter of publication of the final rule. We ask that CMS allow manufacturers one year from publication of the final rule to recalculate and resubmit baseline AMPs.

Nominal Price Reporting

AstraZeneca thanks CMS for providing clear guidance on the definition of qualified entities that can continue to receive nominal pricing without affecting a manufacturer's Best Price. While the definition of qualifying entities is now clear, we ask CMS to provide additional clarification on the actual reporting of nominal pricing information to CMS. Specifically, we ask CMS to clarify if nominal price reporting is at the gross or net level. We assume that CMS expects it to be done at the net level; however, clarification in the final rule would be helpful in assuring the accuracy of our submissions. In addition, we request that CMS include an example of how nominal price data should be reported.

Prompt Pay Reporting
AstraZeneca agrees with CMS' decision to request customary prompt pay submissions on a quarterly versus a monthly basis. However, we ask CMS to provide additional information as to how prompt pay information should be reported to CMS. In the proposed rule, CMS states that prompt pay discounts should be reported at an aggregate level, including discounts paid to all purchasers in the rebate period. As written currently, the statement is too vague to know what level of detail is required. We encourage CMS to include additional specification in the final rule.

Smoothing Methodologies
AstraZeneca agrees with CMS that monthly AMPs may vary markedly if a smoothing methodology is not adopted. As such, we agree with the adoption of such a methodology to minimize volatility. CMS must issue clear, specific guidance as to the processes and assumptions manufacturers must make in conducting a smoothing methodology for monthly submissions. We believe that the existing Average Sales Price (ASP) smoothing methodology would serve as an appropriate proxy, given the time and effort that CMS invested in refining it. We hope that CMS will use the final rule as the vehicle to issue this clarification.

Other Issues Not Addressed in the Proposed Rule:

Use of AMP in Determining 340B Pricing
As CMS is aware, AMP affects the calculation of manufacturers' 340B pricing. It has come to our attention via the Health Resources and Services Administration (HRSA) that there may be a disconnect between the new definition of AMP and the setting of 340B pricing. Currently, the AMP information submitted to CMS is used to set 340B pricing; there is not a separate calculation for the 340B program. However, if CMS were to adopt the HRSA approach, manufacturers would need to use the new definition of AMP for Medicaid purposes, while continuing to report an "old" definition of AMP for 340B pricing purposes (which might even necessitate reporting under pre-1992 standards). We believe that this result was not intended by the DRA, and we implore CMS and HRSA to partner and find a regulatory pathway to resolve this confusion. The calculation and submission of two separate AMPs would impose an unnecessarily heavy operational burden on manufacturers and on CMS. Congress clearly did not intend for manufacturers to make two separate and distinct AMP submissions, as additional workload requirements did not appear to be represented in the workload analysis section of the proposed rule.

Ensuring Appropriate Pharmacy Reimbursement
AstraZeneca's objective is to ensure that patients have access to vital medications. Because the proposed rule on AMP will have implications to pharmacy reimbursement rates, we ask that CMS be diligent in monitoring Medicaid patient access. In particular, we ask CMS to work with the states directly to ensure that all AMP-based reimbursement systems serve as an appropriate proxy for actual pharmacy acquisition costs. It will not be feasible to set pharmacy reimbursement rates at the flat AMP value (aka AMP + 0%), as this would not be representative of all pharmacy acquisition costs. This point was addressed in the recent GAO report entitled *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*[1]. The GAO found that underpayments to retailers were directly related to the fact that retail pharmacy drug acquisition costs were higher than AMP-based rates. Therefore we

[1]December 2006: http://www.gao.gov/new.items/d07239r.pdf

believe, just as in the ASP system, a percentage multiplier would have to be added to the AMP value to ensure that pharmacy acquisition costs do not on average exceed the reimbursement rate.

In addition, as state Medicaid programs reduce overall drug reimbursement by moving to AMP-based systems, it will critical to evaluate the adequacy of dispensing fees. Historically, higher drug reimbursement rates may have been used to offset any losses incurred from low dispensing fees. As drug reimbursement rates are adjusted to more accurately reflect retail acquisition costs, it may be necessary to make commensurate adjustments to dispensing fees. CMS and Congress recognized the importance of increasing physician fees to provide an offset to the drug reductions when implementing the ASP system, so we ask that CMS encourage the states to conduct a careful evaluation to set appropriate dispensing fees in the future.

Updating the ASP Threshold Percentage

As CMS is aware, the use of AMP is not limited to the Medicaid program. In fact, there is a specific provision that allows CMS to substitute 103% of AMP for the Medicare Part B drug reimbursement rate, if CMS finds that ASP exceeds AMP or widely available market price (WAMP) by a certain threshold, which is currently set at five percent. The current threshold was based upon the prior definition of AMP. The new definition of AMP could reduce AMPs for certain products, thus triggering the ASP substitution threshold when it may not have been triggered previously. Although CMS has not elected to utilize AMP or WAMP in place of ASP to date, we ask that CMS carefully observe the differential between the new and old AMPs to ensure that a majority of products remain unaffected by the threshold trigger. This is consistent with the current threshold percentage in that very few products currently trigger the threshold. We do not believe CMS' intention is to begin substituting AMP for ASP for purposes of Part B reimbursement based solely upon the change in the definition of AMP itself. However, we ask that CMS make this statement explicitly in the final rule and continue to carefully monitor the situation to protect access to therapies covered under Medicare Part B.

Conclusion

We thank CMS for considering our comments and we hope they offer valuable insight. We understand the complexity of CMS' task and remain committed to partnering with CMS on an ongoing basis. We would like to close this letter by reiterating our overall recommendations:

- CMS should provide sufficient clarity in regard to the definition of AMP so as to remove ambiguity and/or the potential for variation in interpretation across manufacturers.
- CMS should commit to updating the AMP regulations and other regulations relating to the Medicaid rebate program on a regular basis so that manufacturers have clear guidance in regard to the treatment of new and evolving classes of trade within the retail channel.
- It should be clearly noted in the final rule that the changes to the definition of AMP are prospective in nature.
- AMP data should not be publicly available until such time as all manufacturers have made consistent submissions using the finalized calculations.
- Given that AMP is likely to be used as the index for setting Medicaid reimbursement rates, CMS should carefully evaluate the reimbursement rates developed by states to ensure that the new rates, including dispensing fees, approximate actual pharmacy costs.
- AstraZeneca hopes that CMS will work to ensure continued patient access to essential therapies covered under the Medicaid program.

REM Corporation
265 S. Pioneer Blvd.
Springboro, Ohio 45066
(937) 743-7775
Fax (937) 743-7786

February 5, 2007

Acting Administrator Leslie Norwalk
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-2238-P (AMP Issues)

Dear Acting Administrator Norwalk:

On behalf of REM Corporation, I would like to take this opportunity to provide our comments on the Proposed Rule CMS-2238-P "*Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005.*"

REM Corporation is a small chain of thirteen (13) community retail drug stores located in southern Ohio and south central Indiana. We fill approximately 600,000 prescriptions annually. A majority of our stores are in rural communities with Medicaid prescriptions ranging from 5 to 35 percent our prescription volume.

There are three major concerns:

1. The formula for AMP-based Federal Upper Limits (FUL) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications. The GAO states that AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in a NCPA sample. The entire sample of 77 multiple-source outpatient prescription drugs were on average 36 percent lower than average retail pharmacy acquisition costs. –GAO-07-239R

   Those pharmacies that remain in the Medicaid program will face a contradicting incentive to dispense more profitable, higher cost brand name medications, thus driving Medicaid costs higher.

2. Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement. There is a conflict in the use of AMP as a baseline for reimbursement for pharmacy and an index for rebates manufacturers pay to states. However, if AMP is to accurately serve both purposes, CMS must define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions not available to retail pharmacy. All rebates and price concessions are appropriately included in "Best Price" but should not be included in AMP. -GAO-05-102

   An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates to the pharmacy. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

3. To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid to retail pharmacy. This can be accomplished by:

   a. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.

   b. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBM's are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

   c. Reporting AMP at the 11-digit NDC level to ensure accuracy.

The GAO findings demonstrate the devastating impact the proposed rule will have on our small chain of pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by selling over the counter product when 97% of our business is attributed to pharmaceutical prescriptions.

It is unlikely that states would set dispensing fees high enough to cover the average $10.51 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study conducted by the accounting firm Grant Thornton, LLP.

If these dispensing costs, in addition to drug acquisition costs, are not covered our 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 sates to consider when setting Dispensing Fees.

The definition of "Dispensing Fee" dose not reflect the true cost for our stores to dispense Medicaid drugs. This definition must include the pharmacist's time spent doing any and all of the activities needed to provide prescriptions and counseling, such as communicating by telephone, fax and e-mail with state Medicaid agencies and PBM's, entering in billing information and other real costs like rent, utilities and bank loans with interest.

REM provides additional services such as delivery service, third party administrative help to beneficiaries and accounts receivable. Most importantly, we provide an important health, safety and counseling service by having knowledge of our patient's medical needs. Our pharmacist's can work closely with the doctor to ensure the best drug regimen is offered to the patient.

Thank you for this opportunity to provide our comments on Proposed Rule CMS-2238-P. We hope these comments are constructive in your deliberation to define Average Manufacturers Price (AMP).

Sincerely,

Anthony V. Rattini
Executive Vice President
REM Corporation

66-1 P. 1.

Fino's Pharmacy

PRESCRIPTION DRUGGIST

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

Pittston, Pa. - 18640

February 19, 2007

Leslie Norwalk
acting administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Md. 21244-1850

Dear Ms. Norwalk

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

We are an independent pharmacy located in Pittston, Pa. We are a major provider of pharmacy services in the Community and your consideration of these comments is essential.

The formula for AMP-based federal Upper Limits (FULS) in the proposed rule will not cover pharmacy acquisition costs for multiple Source generic medications.

Fino's Pharmacy

PRESCRIPTION DRUGGIST

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

Pittston, Pa. - 18640

Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement. The use of Wholesale acquisition Cost (WAC) would be better used and is readily available now by pricing services.

To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy This can be accomplished by:

1. Excluding all rebates and price Concessions made by manufacturers to 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 pricing not available to retail pharmacy, independent or chain.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy.

Fino's Pharmacy

PRESCRIPTION DRUGGIST

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

Pittston, Pa. - 18640

#3

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

Sincerely,

Vincent J. Peck. R. Ph.

Fino's Pharmacy

MIAMI-LUKEN, INC.
Full Service Drug Wholesaler

Miami Luken

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

2/6/07

Re: CMS-2238-P (AMP Issues)

Gentlemen:

To provide some background, Miami-Luken, Inc. is a pharmaceutical manufacturer approved wholesale distributor of prescription products. We supply prescription products to approximately 143 independent retail pharmacies in Ohio, Indiana, West Virginia and Kentucky. Most of our customers are located in small rural towns and average about 20% of their business with Medicaid.

Many of these stores have struggled with reimbursement cuts and slow pay from the Pharmacy Benefits Managers (PBM's) and insurance companies. We have seen many stores forced to sell out to the major chains or close as a result of payment cuts and the shift to mail order operations owned by PBM's.

The shift to AMP based generic pricing will result in reimbursements that fall well below the product cost to the retail pharmacies. This will push the business even faster to mail order suppliers who will receive payments well above their cost.

The GAO estimates recently published suggest that pharmacy payments under Medicaid will be approximately 36% below cost using AMP pricing. Recognizing that the labor and overhead to fill a prescription averages about $10.50, suggests that pharmacies will have to turn away Medicaid patients.

The net result of AMP pricing as it now reads is the closing of many pharmacies, the elimination of the only pharmacy in many small towns, increased difficulty finding a

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Medicaid source for many patients, and the shifting of business to those segments of the industry who already get favored prices from the pharmaceutical manufacturers.

We are not opposed to using an average price for generic Medicaid reimbursement, but it must be a true average of what retail pharmacies actually pay for the drugs. We need to create a level playing field where all suppliers pay the same price for prescription products.

Sincerely,
Miami-Luken, Inc.

William M. Powers, Jr.
President & CEO

CHARLES H. HOLCOMBE, R.PH.
PHARMACY SERVICE

166 Converse Drive
Plain City, Ohio 43064

Office (614) 873-8600
Cell (614) 406-5790
holcomcare@aol.com

Memo to CMS

Re: CMS-2238-P

Date: Feb. 6, 2007

Please redefine AMP so that it reflects the amount the small rural pharmacy actually pays for a generic drug. AMP needs to reflect 100% of actual ingredient cost. A clear definition from CMS needs to be issued soon.

Thank you.

Chas H Holcombe RPh

*** RECEIVED ***
Jan 10,2007 10:59:59 WS# 06
OFFICE OF THE SECRETARY
CORRESPONDENCE
CONTROL CENTER

FAX TRANSMISSION

To: Representative Pete Visclosky <http://www.house.gov/writerep>

From:

Subject: Take Action: Define Average Manufacturers Price

Message:

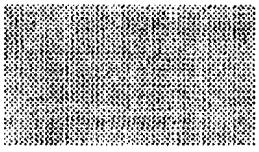
Representative Pete Visclosky
U.S. House of Representatives
2256 Rayburn House Office Building
Washington, DC 205150001
http://www.house.gov/writerep
Fax: 202-225-2493

Dear Representative Pete Visclosky

Beginning in 2007, Average Manufacturers Price (AMP) will become the Federal benchmark for Medicaid pharmacy reimbursement on generic drugs. Each state sets their own pharmacy reimbursement rates, but the implementation of AMP will reduce the Federal funding that states receive, which will likely in turn reduce your reimbursement. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. The Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. Members of Congress can encourage the Secretary to develop the appropriate definition of AMP.
The Average Manufacturer Price, or AMP, will soon become the benchmark for Medicaid reimbursement on generic drugs. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs. Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities.
Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.
Please contact the Secretary of Health and Human Services and urge him to issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.
Thank you for taking the time on this important issue.

Sincerely,
Nathan Damasius

7524 W. 92nd Ave.
Crown Point, IN 46307
219-845-2900
natedam@hotmail.com



Company Name
Address
Tel: Fax:
Email: Website:

Department of Health & Human Services
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601-5519

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Refer to:

JAN 24 2007

The Honorable Peter J. Visclosky
U.S. House of Representatives
2258 Rayburn Building
Washington, DC 20515-1401

ATTN: Catherine Beecher

Dear Mr. Visclosky:

This is in response to your letter to Secretary Michael Leavitt on behalf of your constituents, Nathan and Vyto Damasius. Your constituents are requesting that the Secretary issue a clear definition of the Average Manufacturer Price (AMP) that covers community pharmacy acquisition cost. Your letter was directed to the Centers for Medicare & Medicaid Services' (CMS) Chicago Regional Office because this office oversees the Medicaid program in Indiana.

CMS recently published a notice of proposed rulemaking that includes clarification to the definition of AMP. This proposed rule would implement sections 6001(a)-(d), 6002, and 6003 of the Deficit Reduction Act (DRA) of 2005. Section 6001(c) of the DRA modifies the definition of AMP to remove customary prompt pay discounts extended to wholesalers from the AMP calculation and requires manufacturer to report these customary prompt pay discounts to the Secretary. Currently this proposal is open for public comment through February 20, 2007. At the close of the comment period, CMS will consider all comments to determine if additional changes to the rule are necessary. Our office will be happy to forward your constituents' concerns to the appropriate staff for consideration.

If you have any additional questions please contact Ms. Leslie Campbell, of my staff, at (312) 353-1557 or Leslie.Campbell@cms.hhs.gov.

Sincerely,

Verlon Johnson
Associate Regional Administrator
Division of Medicaid and Children's Health

Region V
Centers for Medicare & Medicaid Services

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Memorandum

Date January 23, 2007

From Chicago Regional Office

Subject Proposed rule 42 CFR 447

To CMS – 2238-P

Refer to

Please find attached copies of comments regarding proposed rule 42 CFR 447 from Nathan and Vyto Damasius that was sent to the Chicago Regional Office.

Enclosures (6)

impact on these facilities would be significant and coming at a time when more than half of the state's hospitals are operating in the red and facing burdensome unfunded mandates, such as seismic retrofitting.

California hospitals are pleased the California's Department of Health Services has identified a possible work-around solution to allow hospitals to continue participation in the 340B Program. However, this proposed solution has not been implemented and it remains to be seen whether it will receive the approvals, etc. necessary to ensure hospitals can continue participation in this important program.

Conclusion

We urge CMS to revise its interpretation of Section 6002 of the DRA and not require the reporting of physician-administered drugs to hospital outpatient or clinic settings. We would be pleased to work with you to ensure the appropriate implementation of Section 6002 of the DRA. If you have questions about our comments, please contact me at slane@calhospital.org or 916-552-7536.

Sincerely,

Sherreta Lane

Sherreta Lane
Vice President, Reimbursement & Economic Analysis

/sl