



American Pharmacists Association

Improving medication use. Advancing patient care.

February 20, 2007

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention CMS-2238-P
7500 Security Boulevard
Baltimore, Maryland 21244

[Submitted electronically to: <http://www.cms.hhs.gov/eRulemaking>]

Re: CMS-2238-P

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the proposed rule, 42 CFR Part 447 – Payment for Services, that was published in the Federal Register on December 22, 2006 (71 FR 77174.) The proposed rule would implement sections of the Deficit Reduction Act of 2005 (DRA) pertaining to reimbursement for generic medications under the Medicaid program. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice settings, and the military.

The proposed regulation would base reimbursement for generic medications on 250% of the Average Manufacturer's Price (AMP), moving away from the current Average Wholesale Price (AWP) model. While APhA appreciates the Agency's efforts to implement the provisions of the DRA and establish a more transparent system for Medicaid prescription medication payments, we are extremely concerned with how the proposed regulation defines AMP and dispensing fees. Our comments will also address authorized generic drugs, exclusions from best price calculations, requirements for manufacturers, Federal Upper Limits (FUL) calculations, physician-administered medications, and specific concerns raised by pharmacies that participate in the 340B Drug Pricing Program within the proposed regulations.

Section 447.502 - Definitions

Dispensing Fee

The proposed regulation carries with it significant responsibility – to establish a fair method to reimburse pharmacies in the Medicaid program for the products they dispense and for services required to ensure safe medication delivery. One of the major goals of Medicaid pharmacy payment reform was to pay pharmacies more accurately for the cost of the drug they dispense as well as more accurately for

their cost of dispensing. Product reimbursement plus dispensing fees should cover the costs and services related to providing medication to Medicaid patients. Unfortunately, the proposed regulation does not give states specific guidance for setting a “reasonable” dispensing fee, and it continues to allow states to determine the “reasonable” dispensing fee required to pay pharmacists. In addition to the product cost component, APhA stresses that pharmacy reimbursement must also include reimbursement for pharmacist services required to dispense the product. Failing to provide guidance on determining an adequate dispensing fee within the overall reimbursement equation may lead payors and policymakers to incorrectly believe that the proposed definition of 250% of AMP would yield sufficient overall reimbursement.

The proposed regulation defines dispensing fee as:¹

- Fee incurred at the point of sale and includes costs other than ingredient cost of a covered outpatient medication each time such medication is dispensed
- Pharmacy costs associated with ensuring that possession of the appropriate covered outpatient medication is transferred to a Medicaid beneficiary. Pharmacy costs include but are not limited to:
 - Reasonable costs associated with a pharmacist’s time checking the computer for an individuals coverage
 - Performing activities related to drug utilization review and preferred drug list review
 - Measuring, mixing, filling, counseling, delivery, providing special packaging, and providing a completed prescription for a covered outpatient medication for a Medicaid beneficiary, and
 - General overhead associated with maintaining the facility and equipment necessary to operate the pharmacy
- Does not include administrative costs incurred by the State in the operation of the covered outpatient medication benefit including systems costs for interfacing with pharmacies.

By comparison, a January 2007 study, *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, identifies the following five main factors that should be included for cost-to-dispense studies:²

- Prescription Department Payroll
- Prescription Department Costs:
 - Prescription containers, labels and other pharmacy supplies
 - Professional liability insurance for pharmacists
 - Prescription department licenses, permits and fees
 - Dues, subscriptions and continuing education for the prescription department
 - Delivery expenses (only prescription-related)
 - Computer systems (related only to the prescription department)
 - Bad debts for prescriptions (including uncollected co-pays)
 - Transaction fees
 - Other prescription-department-specific costs
- Facilities costs

¹ 42 CFR § 447.502.

² Grant Thorton LLP; *National Study to Determine the Cost of Dispensing Prescription in Community Retail Pharmacies*. January 2007.

- Other store/location costs
- Corporate costs allocated to prescription departments

The above five factors include several important elements related to overall pharmacy department overhead and costs not specifically identified in the proposed regulation, including expenses related to: pharmacy payroll; department costs incurred through pharmacy supplies, liability, state and federal fees, continuing education requirements, computer/phone system, debts, and transaction fees. This added detail is a much better representation of the costs that should be included when determining dispensing fees. It is important for the Agency to recognize the broad scope of expenses involved with providing prescription medications to patients which go well beyond the simple cost of the product.

Pharmacies should be paid a fair dispensing fee based on their actual cost of dispensing. The dispensing fee, which reflects professional services associated with providing the product, should be determined annually by an independent actuary (or other contractor) who meets specific criteria and with whom CMS would contract to do cost-to-dispense studies on a regional and/or state basis. States should then be required to either utilize these figures to set their dispensing fees or conduct their own state-specific cost-to-dispense study based on the criteria that CMS outlines. States should be encouraged to account for variances such as urban versus rural and geographical cost differences. However, dispensing fees should not be decreased for safety-net pharmacies that help to provide care for the nation's most vulnerable patients. APhA urges CMS to require states to pay all pharmacies a fair and accurate dispensing fee that actually reflects the pharmacy's true costs for providing medications and services to Medicaid patients. This would help to ensure fair compensation and the continued viability of the pharmacy community. Finally, it would help correct the existing problem that few states currently pay a dispensing fee that is fair and reflective of the services provided.

APhA is concerned that that lack of guidance for defining a dispensing fee would permit state Medicaid programs to continue to underpay pharmacists for their dispensing-related services. While the Medicaid program will be paying pharmacies less for the generic drug ingredient cost, CMS should encourage states to ensure that dispensing fees are adequate and accurate for all pharmacies. For example, the average State Medicaid program pays approximately a \$4 dispensing fee. Unfortunately, based on the recent national study, the average cost to dispense a medication is approximately \$10-12³. The proposed regulations offer no incentives or guarantees for states to provide appropriate reimbursement through dispensing fees to pharmacies. There is also no system in place to penalize states who fail to adequately reimburse pharmacies. Without assurances that community pharmacies will receive adequate reimbursement for pharmacists' dispensing-related services and assurances that pharmacy remains a financially viable practice, Medicaid beneficiaries may unfortunately be faced with decreased access to pharmacist services. Additionally, those pharmacies that continue to work with Medicaid patients may be penalized for continuing to offer their services.

Section 447.504(e) – Determination of Average Manufacturer Price (AMP)

Definition of Retail Pharmacy Class of Trade

The proposed regulation defines AMP as the average price received by a manufacturer from wholesalers for drugs distributed to the retail pharmacy class of trade. The proposal then defines "retail pharmacy class of trade" as:⁴

³ Grant Thornton LLP; *National Study to Determine the Cost of Dispensing Prescription in Community Retail Pharmacies*. January 2007; 15.

⁴ 42 CFR § 447.504(e). 22 December 2006

- 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

Unfortunately, the proposed definition of retail pharmacy, which would be used to calculate AMP, includes prices given to mail-service pharmacies and pharmacy benefit managers (PBMs). APhA is concerned with the Agency's suggestion that these types of pharmacies fall within the definition of retail pharmacy. PBMs do not sell or provide medications to the general public. Additionally, mail-service pharmacies do not dispense medication to the general public and are not accessible in the same manner as community pharmacies. Neither model offers patients the opportunity for face-to-face interaction and consultation with a pharmacist. It is unreasonable to include these entities in the definition of retail pharmacy. These groups may have access to rebates and price concessions that may not be available to community pharmacy. Consequently, APhA is concerned that by including sales to such pharmacies, the AMP-based reimbursement rate may be set lower than the price at which community pharmacies can purchase generic medication products.

Recent reports from the Congressional Budget Office (CBO) and the U.S. Government Accountability Office (GAO) highlight dramatic price differences in the various pharmacy settings. The CBO report noted that community pharmacies do not have access to prescription medication pricing and manufacturer rebates available to mail-service pharmacies.⁵ In addition, the GAO study found that estimated reimbursement calculations, based on the new AMP-based calculation, for 77 of the most frequently dispensed generic medications would be on average 36% below the actual acquisition costs for community pharmacies.⁶ While the studies may not have combined all pricing and medication factors, they illustrate the urgent need to reevaluate how the new AMP-based calculations could negatively impact pharmacy.

As APhA expressed during the Congressional debate on the DRA and in its discussions with the Office of Inspector General (OIG) for its study on this issue, we strongly recommend that the elements used to define and calculate AMP reflect prices actually available to community pharmacy. Otherwise, the reimbursement calculations may not adequately cover the cost to obtain the product. It is critical for the Agency to ensure fair compensation and thus viability of the pharmacies providing services to Medicaid patients, by evaluating all of the costs relative to actual community pharmacy settings.

In the preamble, the Agency states that the majority of the savings to be realized through implementation of the proposed regulation would be felt in pharmacy, based on decreased payments to pharmacies. America's pharmacies should not be asked to bear the brunt of these proposed savings. The Agency estimates that pharmacy revenue may decrease by nearly \$800 million in 2007, despite the fact that no other health care provider or system is asked to manage such changes.⁷ Pharmacy plays a central role for the health care community, especially in rural and low-income settings where the pharmacist may be the only health care provider in the local area. By not providing adequate reimbursement to pharmacy, the changes proposed may negatively impact the ability of pharmacy to continue to serve the Medicaid patient population.

⁵ Congressional Budget Office (CBO). Pub No 2703. Prescription Drug Pricing in the Private Sector. January 2007.

⁶ Government Accountability Office (GAO). GAO-07-239R Medicaid Federal Upper Limits. December 22, 2006

⁷ 42 CFR § 447 p77192-3. 22 December 2006

Section 447.504 (g) – Determination of Average Manufacturer Price

Sales, rebates, discounts, or other price concessions included in AMP

The proposed regulation defines the Federal Upper Limit (FUL) reimbursement rate at 250% of the lowest AMP for a dosage form and strength of a drug. APhA is concerned with the following elements that are included in the calculation of AMP:⁸

- Sales to wholesalers and manufacturers acting as wholesalers, discounts, rebates or other price concessions to Pharmacy Benefit Manager (PBM), sales to mail-service pharmacies, sales to clinic pharmacies and hospital outpatient pharmacies, manufacturer coupons redeemed by any entity other than the consumer.

Unfortunately, these elements do not reflect actual acquisition costs for most community pharmacies. The proposal to include price concessions and rebates available to PBMs, sales to mail-service pharmacies, manufacturer coupons, and sales to clinic and hospital pharmacies does not reflect retail pharmacy costs. Retail pharmacy does not have access to these price concessions, sales or rebates and consequently, APhA is concerned that AMP may be set at a rate lower than what community pharmacy can purchase generic medication products.

Within the preamble discussion of this section, the Agency debates what elements to include in the calculation of AMP and discusses the challenges with developing the proposed regulations. While APhA appreciates the Agency's discussion, we disagree with the conclusion and believe there is insufficient evidence provided for including the listed elements. The discussion noted that by not including the full list of elements for calculating AMP, there may be a risk of an inflated calculation of AMP. Nonetheless, APhA opposes including these elements due to the lack of transparency and consistency from manufacturers in reporting AMP and the lack of understanding of what the calculations will be. This lack of evidence creates an even greater unfair burden on pharmacy to manage decreased reimbursement rates. The decision of what elements to include in the calculation of AMP should ensure appropriate reimbursement to pharmacies and should be based on what rates are accessible to the retail pharmacy class of trade. APhA recommends that the following list be removed from the inclusion list and be added to the exclusion list for the calculation of AMP:

- Sales to wholesalers and manufacturers acting as wholesalers, discounts, rebates or other price concessions to Pharmacy Benefit Manager (PBM), sales to mail-service pharmacies, sales to clinic pharmacies and hospital outpatient pharmacies, manufacturer coupons redeemed by any entity other than the consumer.

We acknowledge the challenges of making the revisions to Medicaid work when AMP was never intended to be used as a benchmark for calculating Medicaid reimbursements. We also realize that Congress established specific requirements for some of these provisions. However, the Agency was given discretion to define AMP and retail pharmacy class of trade, and we urge you to use that discretion carefully. Your decisions on these matters are crucial to the nation's pharmacies, making it absolutely essential that such a shift in reimbursement calculations be determined correctly.

In addition, APhA asks the Agency to consider providing safety-net pharmacies, such as those which participate in the 340B Drug Pricing Program, an exception to use 11-digit National Drug Codes (NDC) numbers for AMP-based reimbursement calculations. While the rule calls for calculations using 9-digit NDC numbers, the 11-digit NCD numbers more accurately reflect actual acquisition costs for 340B

⁸ 42 CFR § 447.504(g)

programs as they capture package size. This exception would apply only to 340B programs as such a change could have significant and unintended consequences for other pharmacies.

Generic Utilization

Additionally, APhA is concerned that the proposed regulations significantly decrease any existing economic incentive for generic utilization for Medicaid patients. The proposed rule does not align with previous efforts and policy to utilize generic medications. The use of AMP to calculate product reimbursement may result in significantly lower reimbursement for dispensing generic medications than brand medications. With this proposal CMS has unfortunately created what may be a disincentive for pharmacy to dispense generic medications. APhA strongly encourages CMS to consider including an incentive for dispensing generic medications by calculating a higher dispensing fee for these drug products. Increasing the dispensing fee for generic medications would create an incentive for pharmacists to dispense these less costly medications that provide savings to the Medicaid program. The increased fee could apply to the dispensing of new and refill prescriptions. Unfortunately, the proposed regulation provides a negative incentive to dispense generic medications to Medicaid beneficiaries. At a minimum, APhA recommends that due to the possible impact on generic utilization, CMS monitor generic utilization rates to determine if there is a decrease in dispensing rates based on the impact of implementing the proposed regulations.

Section 447.506 - Authorized Generic Drugs

The proposed rule states that CMS will interpret the language of section 6003 of the DRA to include in the best price and AMP calculations of the branded drugs the authorized generic drugs that have been marketed by another manufacturer or subsidiary of the brand manufacturer. APhA realizes that Congress required this change, nonetheless we are concerned that the proposed regulation would result in new AMP-based calculations that will apply to more medications, thus compounding the problem of decreased reimbursement to pharmacy for authorized generic medications. This broadened definition of authorized generic medications could create a disincentive for generic utilization, thus increasing costs to the Medicaid program. Again, APhA recommends that due to the possible impact on generic utilization, CMS monitor generic utilization rates based on the impact of implementing the proposed regulations.

Section 447.508 - Exclusion from Best Price of Certain Sales at a Nominal Price

The DRA permits nominal price sales (less than 10% of AMP) for certain listed types of facilities. The DRA also gave the Secretary the authority to designate other types of entities for the exemption. It appears that in this proposed rule, the Agency chose not to exercise that authority. That decision is problematic for two reasons. First, the Agency's decision has created some concern that the Agency does not intend to implement the provision authorizing discretionary exemptions. APhA suggests that the Agency add stronger language in the preamble, or in the text of the Final Rule to clarify that CMS does intend to retain such authority, even if it chooses not to exercise it at this time.

Second, APhA encourages the Agency to exercise that authority and specifically permit nominal price sales to Children's Hospitals without risk of setting a new Best Price. In Section 6004 of the DRA, Congress added Children's Hospitals to the list of entities eligible to participate in the 340B Drug Pricing program. Unfortunately, the DRA amended the Social Security Act, not the Public Health Service Act, which implements 340B. HRSA is working on guidance that would permit Children's Hospitals to participate in 340B, and to require the hospitals to meet all of the requirements of the program. However, in the meantime, Children's Hospitals are not yet permitted to participate in 340B,

and most are no longer receiving nominal price sales on many of their outpatient medications. Consequently, the costs of their medications have risen dramatically. APhA asks the Agency to reconsider its position and use its statutory authority to permit nominal price sales to Children's Hospitals with exemption for Best Price. This action would also alleviate concerns about whether the Agency intends to implement and use the statutory authority, and would help achieve Congressional intent, of providing discounted outpatient drugs to Children's Hospitals under the 340B Drug Pricing Program.

Section 447.510 - Requirements for Manufacturers

APhA is concerned about how safety-net pharmacies, such as those which participate in the 340B Drug Pricing Program, may be effected by the proposed regulation. HRSA uses AMP in the formula to establish the ceiling price for covered outpatient drugs under 340B. The proposed regulatory clarifications of AMP (such as including PBM rebates and price concessions, mail-service prices, administrative and service fees) may lead to changes in how some manufacturers calculate their ceiling prices. In general, it is better for the safety-net community if AMP remains low, because it maximizes the benefit of participation in the 340B program. However, the benefits to the uninsured and other vulnerable patients would be severely minimized if the Medicaid reimbursement cuts had the effect of reducing access to pharmacists.

Another matter for consideration concerns the definition of AMP for the Public Health Service Act (PHSA.) Although the DRA amended the statutory definition of AMP for purposes of Medicaid by removing the deduction for prompt pay discounts, Section 340B(c) of the PHSA states, "Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of the section." Accordingly, HRSA and specifically, the Office of Pharmacy Affairs (OPA) must continue to have access to the data on AMP calculations prior to enactment of the DRA in order to continue calculating the 340B ceiling price according to their statute. APhA urges CMS to work with HRSA to ensure that OPA still has access to the crucial data that is required by statute to calculate the 340B ceiling price.

Section 447.520 - Conditions Relating to Physician-Administered Drugs

The proposed rule also implements a provision of the DRA that requires States to collect rebates on physician-administered drugs (both single source and multiple source drugs) using the NDC numbers or an alternative specified by the Secretary. In the proposal, the Secretary did not specify an alternative coding system, due to the prevalence of the NDC numbers and that they provide the data states need to collect rebates. However, there are significant problems for many hospitals and other healthcare facilities that provide physician-administered drugs. This is the first time states have sought rebates on such medications, and there are technological and other policy concerns.

The technological concerns arise because many states do not currently have Medicaid processing systems that allow for billing National Drug Codes (NDC) for physician-administered drugs, and will need to conduct significant upgrades to their systems and new billing instructions for their providers. Currently, many hospitals bill for their outpatient medications using J-Codes, established by the Healthcare Common Procedure Coding System (HCPCS). Hospitals typically only use NDC numbers for medication ordering and inventory processes. Additionally, there is limited capacity to match J-Codes to NDC numbers for brand products, and none for generics.

Physician-administered drug claims typically use the physician's Medicaid provider number, not the clinic or hospital's Medicaid provider number, which appears in the 340B Medicaid exclusion file. The policy implication for collecting rebates on physician-administered drugs is that it severely diminishes the benefit of the 340B Drug Pricing Program for eligible covered entities. Currently, disproportionate share hospitals (DSH), federally-qualified health centers (FQHC) and other 340B covered entities do not pay rebates on physician-administered drugs. Instead, they are able to purchase these (often high priced) drug products with the 340B discount, which garners considerable savings for the entity. The purpose of 340B was to generate savings for the eligible covered entities, which they can choose to reinvest to the benefit of the entity *and the vulnerable patients that these facilities serve*. The savings generated by participation in 340B can permit a health center to provide free (or greatly reduced) medications and other services to their patients, many of whom are not able to pay. Participation in 340B is a prudent measure for the federally-funded entities that provide care to the underserved, to stretch the Federal dollars. However, if covered entities are now forced to give up the opportunity to purchase these medications under 340B, the impact on the facilities and their patients could be dire. The 340B program protects manufacturers from paying a duplicate discount on the same product (i.e. 340B discount for the entity AND rebates to state Medicaid Agencies.) It would be a perverse result if a statute designed to "reform" Medicaid ended up hurting the neediest patients and the few providers where they receive their care. We urge the Agency to delay implementation of this provision to design an alternative system that will resolve these issues.

Increasing return on investment through medication therapy management (MTM)

Unfortunately, the proposed regulations focus on the medication product and the cost to provide the product, not improving medication use. Simply providing the medication product to a patient may not always be enough to help a patient manage their medication. Patient self-management of medication has proven to be a weak link in the health care system. Pharmacist-provided medication therapy management services can help patients use their medications correctly. Modifications to the Medicaid payment system should consider the role of pharmacists in ensuring appropriate medication use. Studies have shown that for every dollar spent on medications, another dollar of spending results from "drug misadventures."⁹ And others have calculated that drug-related morbidity and mortality in ambulatory patients alone costs an estimated \$177 billion annually.¹⁰ But, nearly 60% of such adverse medication-related outcomes could be eliminated by providing pharmacist care through MTM services.¹¹

As the Agency continues to review potential areas for long-term savings in the Medicaid program, APhA urges the Agency to consider the role of the pharmacists in ensuring appropriate medication use through pharmacist-provided medication therapy management (MTM) services. MTM services for Medicaid beneficiaries would offer a way to improve patient care and reduce health care expenditures in the overall Medicaid program.

MTM programs compensate pharmacists for providing a range of clinical services to patients, including thoroughly educating a patient about their medication and the condition for which it is prescribed, reviewing a patient's medication regimen and developing a medication action plan to address identified

⁹ Brooks JM, McDonough RP, Doucette W. Pharmacist reimbursement for pharmaceutical care services: Why insurers may flinch. *Drug Benefit Trends*; June 2000; 45-62

¹⁰ Ernst FR, Grizzle, AJ. Drug-Related Morbidity and Mortality; Updating the Cost-of-Illness Model. *Journal of the American Pharmaceutical Association*; 2001 Mar-APR; 41(2);192-199.

¹¹ Johnson JA, Bootman JL. Drug related morbidity and mortality and the economic impact of pharmaceutical care. *American Journal of Health System Pharmacy*; 1997; 54:554-558.

issues, monitoring the patient's drug therapy over time, screening for potential adverse effects of medication, and monitoring a patient's ability to take their medications correctly.¹² By providing an incentive for pharmacists to spend additional time with patients, Medicaid programs could optimize therapeutic outcomes, improve medication use, reduce the risks of adverse events and drug interactions, and increase patient adherence and compliance with medications. Again, APhA emphasizes that future Medicaid payment reform should include compensation for pharmacist-provided MTM services.

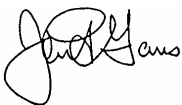
In the DRA and the proposed rule to implement it, Congress and the Agency have suggested that savings to the Medicaid program could largely be realized through reduced Medicaid payments to pharmacies for generic medications and that reimbursement based on 250% of AMP should be sufficient to reimburse the pharmacy. However, this assumption was challenged in the recent GAO report that found that the new reimbursement formula may result in an in reimbursement of community pharmacies at 36% below their average acquisition cost for generic medications.¹³ Pharmacy should not be forced to choose between participating in the Medicaid program and receiving fair and adequate reimbursement for costs associated with providing services to Medicaid patients.

Thank you for the opportunity to provide comments on this important issue. APhA supports the Agency's intent to implement a more transparent system for paying for medications but the system also must provide adequate payment to cover pharmacies' costs. With inadequate payment, pharmacies may be forced to limit access to pharmacy services for Medicaid beneficiaries.

APhA recommends that the Agency continue to work with pharmacist and pharmacy organizations to establish an appropriate payment formula. To that end, we offer our assistance as you continue your important work to impellent an appropriate payment system for prescription mediations through the Medicaid program.

We look forward to continuing to work with the Agency. If you have any questions or require any additional information, please contact Marcie Bough, Director of Federal Regulatory Affairs at (202)429-7538 or at MBough@APhAnet.org.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Catherine M. Polley, RPh, Senior Vice President, Government and Professional Affairs, Chief Policy Officer
Marcie A. Bough, PharmD, Director, Federal Regulatory Affairs.

¹² Bluml B. Definition of medication therapy blagement; development of profession-wide consensus. *Journal of the American Pharmacists Association*. 2005;45:566-72.

¹³ Government Accountability Office (GAO). GAO-07-239R Medicaid Federal Upper Limits. December 22, 2006