October 4, 2010

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

Subject: Medicaid Program: Withdrawal of Determination of AMP, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs (CMS 2238-P2; RIN 0938-AP67)

To Whom It May Concern:

The National Community Pharmacists Association (NCPA) is writing to support the proposed regulation to modify the final regulation “Medicaid Program: Prescription Drugs” that was published in the Federal Register on July 7, 2007. The sections that are proposed to be withdrawn are Section 447.504, “Determination of AMP; Section 447.514, “Upper Limits for Multiple Source Drugs”; and the definition of multiple source drug in Section 447.502, as it was amended by the multiple source drug rule published on October 7, 2008.

NCPA represents the owners and operators of approximately 23,000 independent community pharmacies in the United States. We believe that it is appropriate that CMS withdraw these sections of the regulation, as Congress recently amended several sections of Section 1927 in the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148) that will require that CMS promulgate new proposed regulations regarding these particular issues.

NCPA has long held that in the final 2007 regulation, CMS did not implement the provisions of the Deficit Reduction Act (DRA) of 2005 consistent with Congressional intent. Among our concerns were the inappropriate definition of AMP to include prices not paid by community retail pharmacies and the use of a definition of “multiple source drug” that was inconsistent with the statute. Several independent economists certified that CMS’s planned implementation of the original DRA law would have closed some 11,000 community retail pharmacies – some 20 percent of all pharmacies – and many independent pharmacies. When issuing a new regulation, CMS should require that manufacturers include in calculation of AMP only those prices that they can document were paid by wholesalers for drugs that were subsequently sold to community retail pharmacies.
With respect to implementation of PPACA, we remain very concerned about the lack of direction and specificity given to manufacturers by CMS at this point regarding the calculation of the new AMPs, which are supposed to go into effect on October 1, 2010. While the PPACA statute includes more specificity than did the original law regarding the prices and discounts to be included in AMP, manufacturers need more specific guidance and interpretation. For that reason, we ask that CMS delay implementation of any new FULs for multiple source drugs until a more precise definition of AMP is determined through the standard notice and comment rulemaking process. We also ask that AMPs not be made public until such time as a regulation is final that will assure consistency among manufacturers in the calculations of AMP.

In addition to more specificity regarding the calculation of AMP, CMS needs to allow for public review and comment on a definition for what constitutes a “multiple source drug that is available for purchase by retail community pharmacies on a nationwide basis”, as well as detail the required smoothing process for discounts to minimize any potential fluctuations in AMP from month to month. Without these critical components defined, it would be unfair to pharmacies, patients, and state Medicaid programs to calculate FULs for generics.

**Regulatory Impact Statement**

NCPA is concerned that CMS indicates that the “proposed rule will not have a significant impact on a substantial number of small entities.” While withdrawing the parts of the existing flawed regulation in question will undoubtedly help maintain the economic viability of some community retail pharmacies, serious concerns remain regarding the implementation of the new PPACA law. While PPACA did restore some of the cuts to Medicaid pharmacy reimbursement that were included in the DRA, we believe that the DRA cuts were so severe that this partial restoration by PPACA could still result in many pharmacy closures and a reduction in patient access to pharmacies, especially in urban and rural areas.

CMS should also consider that millions of additional Medicaid patients will be added to the program by 2014 under the new health reform law. This means Medicaid will have an even greater influence on pharmacy margins in the very near future. CMS should undertake a more analytical regulatory impact analysis on community retail pharmacies when the new regulation is proposed, considering the following facts:

- **Original Medicaid Pharmacy Generic Reimbursement Cuts Were Very Severe:** The original DRA cuts to pharmacies were expected to total $11.8 billion between 2007 and 2015. Based upon a sample of drugs studied by the OIG, implementing DRA cuts would have underpaid pharmacies on 52% to 76% of drugs studied.\(^1\)\(^2\) The GAO estimated that these cuts would reimburse pharmacies between 17 to 36 percent below their costs of buying generics,\(^3\)\(^4\) and another study found that 11,000 pharmacies\(^5\) – mostly smaller pharmacies – would close.

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\(^1\) A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices. OEI-03-08-00490, August 2009.


\(^3\) Medicaid Outpatient Prescription Drugs: 2008 Federal Upper Limits for Reimbursement Compared with Average Retail Pharmacy Acquisition Costs. GAO-10-118R, November 2009.
• Community Pharmacies Derive a Larger Percent of Prescription Revenues from Medicaid: For the average independent community pharmacy, over 90% of all revenues are derived from prescription sales, and 14.5% of all prescriptions revenues are from Medicaid. This is almost twice as high compared to larger pharmacies where on average only 7.5% of prescriptions are filled through Medicaid. Thus, prescription revenues are not marginal business to independent community pharmacies. Moreover, expansions of the Medicaid program in 2014 will mean that a higher percentage of community pharmacy revenues will be derived from Medicaid.

• Community Pharmacies are Located Predominantly in Urban and Rural Areas: Although independent community pharmacies comprise less than 39% of all pharmacies nationally, the number of independents in rural areas outnumbers the total number of larger pharmacies. Amongst all rural pharmacies, 52.5% are independent community pharmacies. Rural patients’ access to pharmacies will be compromised if the Medicaid cuts are not restored to a sufficient level.

Implementation of Amendments made by P.L. 111-226
Under the changes made in PPACA, manufacturers can only include prices paid by wholesalers for drugs sold to community retail pharmacies when calculating their AMPs. However, we understand that the Department needs manufacturers to be able to accurately calculate AMPs for certain multiple source drugs – such as infusion and injection drugs – for the purpose of state rebate collections. In some cases, these drugs are sold to other outlets than retail community pharmacies, necessitating the inclusion of non-retail prices in the AMPs. Section 202 of P.L. 111-226 requires that manufacturers exclude non-retail pharmacy prices from the calculation of the AMP “…unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.”

However, as CMS knows, these AMPs are also used to calculate Federal reimbursement limits for multiple source drugs for community retail pharmacies. Including the prices of these other non-retail pharmacy purchasers in the calculation of AMP, and thus the calculation of FULs, could underpay retail community pharmacies for multiple source drugs. We believe that a drug is not generally dispensed through a retail community pharmacy only if 90 percent or more of unit sales are not dispensed by retail community pharmacies. That is, if 10 percent or more of manufacturers’ unit sales are to retail pharmacies then the drug is generally dispensed through a community retail pharmacy. In these cases for individual dosage form and strength of a manufacturer’s drug, then the manufacturer cannot include these other non-retail

8 All analysis regarding the distribution of pharmacies is based upon an internal NCPA analysis of National Council for Prescription Drug Programs (NCPDP) data for August of 2009.
prices. We believe this will accurately and appropriately implement the provision that requires that these non-retail prices be included only if the drug is not generally dispensed through a community retail pharmacy.

Moreover, unless these products are widely available to community pharmacies on a nationwide basis, CMS should not be calculating a FUL for these drugs. If a drug is not widely available to community pharmacies, the likelihood is that it is not widely available on a nationwide basis for purchase by pharmacies. For that reason, any drug in this limited category that includes prices other than community pharmacy prices should not have a FUL.

While PPACA does give CMS the authority to use a higher multiplier than 175 percent to calculate the FUL for certain multiple source drugs, we do not believe that these specific drugs would meet the original test for the setting of an FUL by being widely available for purchase by community retail pharmacies.

Thank you for your interest in NCPA’s views on these issues. We look forward to reviewing any future regulations on this issue.

Sincerely,

John M. Coster, Ph.D., R.Ph.
Senior Vice President, Government Affairs