November 3, 2011

Cindy Mann, Director
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Subject: Second Draft AMP-Based FULs for Medicaid Multiple Source Drug Reimbursement

Dear Cindy:

On behalf of the National Community Pharmacists Association, I am writing regarding the second draft Average Manufacturer Price ("AMP") based Federal Upper Limits ("FULs") list for multiple source drugs released by CMS on October 21st. We appreciate the opportunity to review the second list before it is possibly required to be used by the states for multiple source drug reimbursement. NCPA represents the owners and operators of approximately 23,000 privately-held small business independent community pharmacies across the United States. We provide about 41 percent of all outpatient prescriptions in the United States.

As was the case with the first list released by CMS in September, we continue to respectfully request that CMS not finalize the draft FULs due to serious shortcomings that would result in devastating economic consequences for small business community pharmacies that serve Medicaid patients. There continue to remain hundreds of drugs on the second list where the FULs are lower than the current market-based acquisition costs for small business community pharmacies. If this set of FULs is implemented, it could result in the loss of access to community pharmacies for Medicaid patients. This could result in negative health consequences and sharply increased Medicaid costs for other health interventions if Medicaid patients cannot obtain their prescription medications. In addition, setting the FULs at levels below the acquisition cost for generics would likely result in higher drug costs overall as it reduces incentives for pharmacies to dispense generic drugs.

As we indicated in the October 17th letter to you regarding the draft September 22nd FUL list, we believe that CMS should not publish AMP-based FULs until a final regulation is issued and at least several months of AMP data have been collected and analyzed by CMS. The result of our analysis of the second draft list follows.

Independent Pharmacy Acquisition Costs Exceed 175% AMP: We remain concerned that AMP is not an accurate representation of the acquisition costs of small community pharmacies. This is evidenced by the fact that, even at 175% of the weighted average AMP, our cost of goods remains much higher than the FULs for many products on this list. In fact, in our analysis of the list, and several other analyses we have seen or are aware of, there are hundreds of products on the list whose FULs are below our acquisition costs.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

For example, in our analysis of the first draft FUL list, 42 percent of the FULs were lower than small pharmacies' acquisition costs, while 58 percent were above the acquisition costs. In our analysis of this new list, which has a higher number of drugs with FULs than the first list, 38 percent of the FULs were lower than pharmacy acquisition costs, while 62 percent were above pharmacy acquisition costs. However, the FULs that were lower than our acquisition costs were for more highly utilized prescription drugs than those that are higher than our acquisition costs.

A recent OIG report confirms that AMP is the least consistent reimbursement benchmark when compared to pharmacy invoice prices. (OIG: Review of Drug Costs to Medicaid Pharmacies and their Relation to Benchmark Pricing, October 2011. A-06-00002). The report also found that it will make a multiplier higher than 175% of AMP just to get FULs to a level equal to pharmacy acquisition costs, and this is particularly the case for smaller independent pharmacies. For example, the report found:

- For multiple source generic drugs without a Federal Upper Limit, rural independent pharmacy acquisition costs are 221% of AMP, while for urban independent pharmacies, they are 203% of AMP.

- For multiple source drugs with a Federal Upper Limit, the acquisition costs of rural independent pharmacies are 249% of AMP, while for urban independent pharmacies they are 240% of AMP.

Given that state dispensing fees are generally paying pharmacies a fraction of their actual dispensing costs, pharmacies continue to need to make some "margin" on product reimbursement to remain in business. This is especially true since Medicaid is not "marginal" business to the average independent pharmacy, and the number of Medicaid patients is expected to increase significantly in 2014. Paying pharmacies at only 175% weighted average AMP – or lower as many states will do – is simply insufficient to cover pharmacy costs of purchasing and dispensing Medicaid prescriptions.

This argues for CMS to set a higher FUL for independent pharmacies which, according to this report, have higher acquisition costs than publicly traded chains. The statute requires that CMS set the FUL at "no less than" 175 percent of the weighted AMP. However, it implicitly grants the Secretary the flexibility and authority to set the FULs at a higher rate that recognizes the variance in acquisition cost by small community pharmacies as compared to large chain pharmacies. Given the vital role independent community pharmacies have in serving Medicaid patients, we urge CMS to use this authority to increase the FULs for privately held community pharmacies beyond the minimum 175% weighted average AMP. The need to use this authority is critical, given the potentially dire impact that these FULs will have on smaller pharmacies.

Small Pharmacies Adversely Impacted by New FULs: Despite aggressive, continuing efforts to negotiate and obtain lower prices, our small business community pharmacies, including smaller chains, purchase generic drugs at a relative premium. This can result in acquisition costs that are often at least 25% to 50% higher than those of publicly-held chain pharmacies. For that reason, small pharmacies will likely always face tighter margins for prescriptions dispensed to Medicaid beneficiaries than national chains for the same multiple source drug.

This has been also recently confirmed by the OIG report, which found that:

- For multiple source generic drugs without a Federal Upper Limit, the average urban independent buys 50% higher than an urban chain. A rural independent buys at a third higher than a rural chain.

- For multiple source generic drugs with a Federal Upper Limit, the average urban independent buys 80% higher than an urban chain. A rural independent buys at about 40% higher than a rural chain.

An analysis of the data clearly shows the negative impact the draft FULs will have on independent pharmacies if implemented in their current form. Using the new second draft FULs, we have re-priced the total reimbursement that different independent community pharmacies would receive under the new FULs compared to current reimbursement. We analyzed a sample of low-volume, medium-volume and high-volume Medicaid pharmacies. The results speak for themselves. The average revenue lost per pharmacy is $43,802, an increase of 30% from the losses from the first draft FUL list.

An example by type of pharmacy is illustrated in the table below. The low volume Medicaid pharmacy would suffer a 38% reduction in reimbursement; the medium volume Medicaid pharmacy a 39% reduction; and the high volume a 38% reduction in reimbursement. These types of reductions are unsustainable.

	Current Reimbursement	New Reimbursement	Percent Reduction
Low-Volume Pharmacy	$59.019	$36,712	38%
Medium-Volume Pharmacy	$89,796	$54,755	39%
High-Volume Pharmacy	$196,233	$122,109	38%

We again urge CMS not to publish the FUL list until a final AMP regulation is public. These draft FUL lists, combined with the recent OIG report showing the lack of relationship of AMP to pharmacy invoice prices, demonstrate how precarious it is to use AMP as a reimbursement benchmark, and how a multiplier higher than 175% can be justified. Use of AMP is made even more dangerous given that CMS has not yet made final a consistent set of rules on how this entire reimbursement system will work. Moreover, it is clear that sound policy would argue for a higher FUL for independent pharmacies and small chains who, through no fault of their own, have higher costs of goods as compared to larger chains. We appreciate your consideration of these views as the agency considers next steps. Thank you for your attention to this matter.

Sincerely,

John M. Coster

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

cc: The Honorable Max Baucus, Chairman Senate Finance Committee
The Honorable Orrin Hatch, Ranking Member, Senate Finance Committee
The Honorable Fred Upton, Chairman, House Energy and Commerce Committee
The Honorable Henry Waxman, Ranking Member, House Energy and Commerce Committee
Rima Cohen, Counselor to the Secretary
Larry Reed, CMS Medicaid Pharmacy Team