

December 5, 2011

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

**Subject: Third 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 third draft Average Manufacturer Price (“AMP”) based Federal Upper Limits (“FULs”) list for multiple source drugs released by CMS on November 21st. We appreciate the opportunity to review the third 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. Moreover, more than 90% of our business is derived from prescription revenues, and Medicaid represents an average 15% of all prescriptions filled. This Medicaid percentage is higher for pharmacies in urban and rural areas.

As was the case with the first and second lists released by CMS in September and October, 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 third 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. This will also be devastating for small businesses at a time when they are trying to maintain good-paying jobs and prevent layoffs or closures.

As we indicated in both the October 17<sup>th</sup> and November 3<sup>rd</sup> letters to you regarding the draft FUL lists, we continue to strongly 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 third 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.

For example, in our analysis of the third draft FUL list, 34 percent of the FULs were lower than small pharmacies' acquisition costs, while 66 percent were above the acquisition costs. As we have said before, based on our experience, most states will reimburse less than the FULs. Therefore, it cannot be assumed that states will maintain the reimbursement at the FUL for those products whose FULs are above pharmacy acquisition costs, offsetting the loss from those that are not.

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.

An example by type of pharmacy is illustrated in the table below. Based on this third draft FUL list, the low volume Medicaid pharmacy would suffer a 38% reduction in reimbursement; the medium volume Medicaid pharmacy a 40% reduction; and the high volume a 40% reduction in reimbursement. These types of reductions are unsustainable and will compromise access and patient care.

	<u>Current Reimbursement</u>	<u>New Reimbursement</u>	<u>Percent Reduction</u>
Low-Volume Pharmacy	\$58,539	\$36,333	38%
Medium-Volume Pharmacy	\$87,208	\$52,454	40%
High-Volume Pharmacy	\$191,733	\$116,544	40%

**New Reimbursement Systems Must Work Together:** We also urge that CMS consider how these new FULs would work with the new proposed National Average Drug Acquisition Cost (NADAC) file which CMS seems intent on publishing. No FUL should be set below the NADAC. States will simply not pay pharmacies above the FUL at 100% of their own costs if the NADAC is higher than the FUL. Unless the NADAC and the FUL are correlated, it will defeat the purpose of generating Federal or state NADAC files. In fact, an examination of the Alabama AAC files shows that many of the draft FULs are set below the AAC file. While we cannot predict for sure what states will do, we would assume that Alabama would reduce their AAC to the NADAC, otherwise they must assume 100% of the cost above the FUL.

In summary, 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. The reports also show how a multiplier higher than 175% can be justified, especially for small independent pharmacies. 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.

Finally, CMS is proposing to release another data set – NADAC – but the agency must be certain that this system can work in tandem with whatever final FUL system is implemented. States will simply not reimburse pharmacies above the FULs at the state’s own cost, even if the NADAC or their own acquisition cost surveys show that pharmacy purchase prices are higher than the FULs. 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, 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