October 17, 2011

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

Subject: 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 draft Average Manufacturer Price ("AMP") based Federal Upper Limits ("FULs") for multiple source drugs released by CMS on September 22nd. We appreciate the opportunity to review the list before it is 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% of all outpatient prescriptions in the United States.

Based on our analysis of the list, we 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 are simply too many drugs on the 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.

For our community pharmacies, adequate Medicaid reimbursement is critical. More than 90 percent of our total store revenues are derived from prescriptions, and Medicaid revenues represent more than 14 percent of the average small pharmacy's prescription revenues. However, more than half of our pharmacies are located in rural communities where many Medicaid patients live. Sometimes we are their only primary health care provider. In these towns and cities, our community pharmacies disproportionately rely on Medicaid revenues to keep their doors open and serve the community's health care needs. These community pharmacists reduce costs for Medicaid and taxpayers by maximizing the appropriate utilization of lower-price generic drugs and by providing expert, face-to-face counseling to promote the proper use of medications as prescribed for patients.

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We recently estimated that Medicaid and Medicare Part D cuts combined over the last 5 years have reduced independent pharmacy revenues by $15 billion, or 17 percent of our gross margin. As a result, there is a 64% increase in independent community pharmacies operating at a loss. Additional cuts to Medicaid reimbursement could devastate many small pharmacies. We have several analytical and policy concerns regarding this list, which we detail here:

No Relation to Cost of Goods: 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 just one analysis, 42 percent of the FULs are lower than small pharmacies' acquisition costs. While 58 percent may be above the acquisition costs, our experience with states are that their State Maximum Allowable Costs (SMACs) are almost always set at rates that are lower than FULs. Moreover, the FULs that are lower than our acquisition costs appear to be for more highly utilized prescription drugs than those that are higher than our acquisition costs. Finally, states are very likely to impose SMACs on products that do not qualify for an FUL, thus putting even greater pressure on acquisition costs misalignments than represented by the FUL list by itself.

Inconsistency in Manufacturer AMP Calculations: While the statute does give CMS the authority to set FULs without a final regulation, we firmly believe that the new AMP regulation should be finalized before any AMP values are used to set FULs. We believe that the lack of specificity regarding how manufacturers are required to calculate AMP values is contributing to the significant amount of variability and distortion we are finding in these FULs. Given the lack of specific guidance, there are likely wide differences in the way that manufacturers are calculating AMP. For example, there are many definitions from the ACA that have yet to be defined for manufacturers, including bona fide service fees, returns, credits, and others, which leaves significant ambiguity in the calculations, and defers this discretion to manufacturers.

Moreover, because AMPs are also used to calculate Medicaid rebates, we believe that manufacturers may, within the discretion given them due to the lack of specific guidance, seek to try and lower their AMPs in order to limit their rebate exposure. This obviously negatively affects the calculation of the FULs. A final rule regarding the AMP definition is needed to eliminate these ambiguities and ensure that AMP values are calculated with more consistency.

Lack of Smoothing of Data: It is inappropriate to base FULs on one month's AMP data, as was done in the calculation of these draft FULs. The statute merely requires that FULs will be *no less than* 175 percent of the weighted AMP of the most recently reported monthly average AMPs while simultaneously requiring a "smoothing process" similar to the process used in calculating the Average Sales Price ("ASP") for Part B drugs under section 1847A.

In fact, there may be several manufacturers whose AMPs may be artificially low in July because the manufacturer may have paid a disproportionate percentage of rebates, discounts or other price concessions in that month. This distortion in the calculation of the weighted AMP, and thus the likely flaw in the draft FULs as calculated, would be even more pronounced if such a manufacturer has a significant share of the market. Section 1927(e)(5) specifically calls for a smoothing process to avoid the type of wild fluctuations that would otherwise likely be seen from month to month in AMP calculations. Using one month's data to calculate AMPs is likely contributing to the type of distortions that we observe in the current data file.

No Indication that Nationally-Available Products Used: Section 1927(e)(5) requires that FULs only be set with AMPs of multiple source products that "are available for purchase by retail community pharmacies on a nationwide basis." We do not believe that the draft FUL list meets this test. There is no indication that CMS excluded multiple source products that are distributed regionally or that are in short supply.

Purchasing Capabilities of Small Pharmacies: 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.

The statute requires that CMS set the FUL at "no less than" 175 percent of the weighted AMP. 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.

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 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. An example is illustrated in the table below. The low volume Medicaid pharmacy would suffer a 44% reduction in reimbursement; the medium volume Medicaid pharmacy a 41% reduction; and the high volume a 38% reduction in reimbursement. These types of reductions are unsustainable.

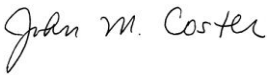
	Current Reimbursement	New Reimbursement	Percent Reduction
Low-Volume Pharmacy	$44,199	$24,799	44%
Medium-Volume Pharmacy	$67,705	$39,735	41%
High-Volume Pharmacy	$146,040	$91,344	38%

Outdated Data: Even if CMS publishes FULs monthly, the values will be outdated almost immediately because several months will have already passed since the AMPs used to calculate the FULs had been reported. During this time, generic manufacturers may have increased prices on some products significantly, meaning that pharmacies will be underpaid. We are seeing this happen in the market today, especially with topical products. However, when community pharmacies appeal to the states to increase their MACs, the states point to the FUL list as the reason why they cannot increase their MAC. This is another reason why CMS should use its authority to increase the FUL beyond the 175% weighted average AMP, especially for small business pharmacies. In addition, we need an appeal process to make CMS aware of sudden changes in the market so that an FUL can be increased or suspended.

Inclusion of Non Generics in Calculations: We believe that there are several cases in the calculations of the draft FULs where brand name products were included or products available in an immediate release and extended release formulations—which have very different price points--were calculated as one product. There are also some cases where OTC products were included. These should not be grouped together with the same dosage form and strength of a particular multiple source drug.

In conclusion, we believe that the draft FULs are significantly flawed and, if implemented, will cause significant economic hardship for privately held small business community pharmacies. We only operate at a small net 3% pre-tax profit margin, so even the smallest changes in reimbursement can make the difference in whether a small business stays open or closes. We believe that CMS should finalize the AMP regulation, collect and analyze several months of new AMP data, assure that only nationally-available products are used, institute the required smoothing process in the calculation, use its discretion to calculate FULs at higher than 175% for privately held pharmacies, and republish a draft list for comment before any FULs are applied. The health of Medicaid patients depends on getting these correct. Once again, thank you for the opportunity to review the list and thank you for your consideration of this request.

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