August 1, 2014

Cindy Mann, Deputy Administrator and Director
Center for Medicaid and CHIP Services
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Administrator Mann:

I am writing today on behalf of the National Community Pharmacists Association (NCPA) to share our observations and thoughts on the Patient Protection and Affordable Care Act (PPACA) based Federal Upper Limits (FULs) and the National Average Drug Acquisition Cost (NADAC) price benchmark for Medicaid-covered outpatient drugs. In addition, we are writing to provide recommendations on needed CMS guidance for states to utilize when considering Medicaid pharmacy reimbursement in order to ensure robust beneficiary access to needed medications.

NCPA represents the owners and operators of the 23,000 small independent pharmacies in the United States which serve as a primary source of health care and prescriptions for Medicaid patients in outpatient and long-term care settings. More than any other segment of the pharmacy industry, independent pharmacies are often located in underserved and rural areas that are home to Medicaid recipients. In fact, independent pharmacies represent 52% of all rural retail pharmacies and there are over 1,800 independent community pharmacies operating as the only retail pharmacy within their rural communities.[1]

FUL Trends Remain Troubling for Small Pharmacies

The draft FUL lists that CMS has released to date based on Average Manufacturer Price (AMP) continue to demonstrate a significant percentage of products in which the FUL is lower than the acquisition cost for drug products available to our members. An NCPA analysis of six draft three-month rolling average FUL lists taken together, shows that 46.74% of the FULs were lower than their comparable NADAC values. In addition, the average loss per unit product has steadily increased over the six drafts analyzed by NCPA. Past experience suggests that states often will reimburse less than a product's FUL and it cannot be assumed that states will maintain reimbursement at the FUL for those products whose FULs are above pharmacy acquisition costs, to offset losses from those that are below.

In light of the continued volatility of the draft AMP-based FULs, NCPA certainly appreciates the recent action of CMS to delay the implementation of the FULs. However, we believe that the AMP-based

[1]Based on NCPA Analysis of National Council for Prescription Drug Programs (NCPDP) data, Rural Urban Commuting Area (RUCA) Codes, and 2000 U.S. Census data.

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

FULs in general are fundamentally flawed and are not an accurate reimbursement metric that should be used to set state Medicaid pharmacy reimbursement on a drug-by- drug basis.

Pharmaceutical manufacturers as a group do not use consistent rules in the reporting of AMPs and have a vested interest in keeping them as low as possible in order to minimize the amount of Medicaid rebates they are required to provide. Variations in AMP reporting from manufacturer to manufacturer occur based on differences in their interpretations of the limited available AMP guidance and, perhaps also, the amount of risk they are willing to incur. Batch manufacturing, API back orders, manufacturing problems, lags in the availability of price concession data because of the operation of the wholesalers' chargeback systems and the extension of discounts through a rebate process as well as general price fluctuations in the competitive marketplace for multiple-source drugs all contribute to unpredictable, often large, fluctuations in AMP from month to month.

As a result, we have serious concerns that the use of the AMP based FULs on a drug-by-drug basis for the purposes of Medicaid pharmacy reimbursement will present insurmountable challenges to the ability of independent pharmacies to continue to provide needed medications and services to Medicaid beneficiaries, resulting in delays and barriers to patient care.

NCPA Is "Cautiously Optimistic" about NADAC

Although the NADAC reimbursement benchmark is relatively new, the files that have been published thus far seem to indicate a fairly accurate accounting of retail pharmacy acquisition costs. In our view, the NADAC as currently calculated at the pharmacy invoice level should be viewed as a more stable and accurate alternative to the use of the AMP-based FULs for the purposes of state Medicaid pharmacy reimbursement.

Critical Need for CMS Guidance to States

While NCPA recognizes that CMS cannot require States to utilize one particular benchmark over another, it would be extremely helpful if CMS would provide guidance, as expeditiously as possible—either in any final AMP Rule or in stand-alone guidance documents—on a number of topics to help clarify the appropriate uses of and consequences of using AMP-based FULs and NADAC.

1. **NCPA recommends that CMS provide guidance to the States that AMP-based FULs should be used only in the aggregate and should not be used on a drug-by-drug basis in any State "lower of" reimbursement algorithm or in a State's MAC methodology.** Given the continued volatility of the FULs, NCPA believes that such guidance is duly warranted and necessary to ensure appropriate state Medicaid pharmacy reimbursement.

2. **NCPA recommends that CMS provide guidance to States saying that if a State uses the NADAC, it does not have to affirmatively prove to CMS that its total expenditure on multiple-source products is below the FULs considered in the aggregate—rather, the State will be presumed to be in compliance with federal statute.** It is our understanding that in the six

states that have established their own state-specific acquisition-cost based reimbursement and the three states that have recently decided to use NADAC— multiple source drug expenditures have consistently been lower than the aggregate FUL cap. NCPA feels that guidance on this subject will provide States with a greater comfort level in using the NADAC.

3. **NCPA recommends that CMS provide guidance to States that with a shift to any acquisition-based pharmacy reimbursement metric, it is critically important to provide for an adequate professional dispensing fee**. In establishing an appropriate professional dispensing fee, it is essential that an appropriate cost of dispensing survey be conducted that takes into account a variety of factors including the overhead expenses involved in owning and operating a pharmacy as well as the professional counseling and other clinical services provided.

   States should also be encouraged to take into consideration certain additional factors such as the total number of Medicaid prescriptions a particular pharmacy fills annually or the percentage of their total prescription volume that is made up of Medicaid prescriptions when setting dispensing fees. For example, pharmacies that serve a significant number of Medicaid beneficiaries or where Medicaid claims comprise a certain percentage of total prescription volume would receive an additional amount added to the base dispensing fee. States could also provide a similar "incentive" in those pharmacies in which generics make up at least a certain percentage of their total prescription volume.

   Finally, States should strongly consider allocating additional amounts for long-term care or specialty pharmacies to account for the higher costs incurred and the additional services provided by these entities. A 2013 study conducted by the Virginia Commonwealth University School of Pharmacy clearly illustrates the additional costs (additional staffing and packaging) incurred by independent pharmacies in filling prescriptions for residents of LTC facilities.[2]

Conclusion

NCPA greatly appreciates the opportunity to share these observations and recommendations with CMS. Given the expansion of Medicaid in many states, it is imperative that there be a sufficient number of pharmacy providers to ensure that all beneficiaries have adequate access to services. Therefore, we feel that it is critical that issues of reimbursement are dealt with in a comprehensive and coordinated way. In addition, we would urge CMS and state Medicaid programs to make greater use of community pharmacy providers to most appropriately manage the drug therapies of Medicaid recipients, thereby maximizing positive patient outcomes and lowering overall costs. We welcome the opportunity to work with CMS and thank you for the consideration of our views.

---

[2] Carroll, Norman V.: *Analysis of Costs to Dispense Prescriptions in Independently Owned Long Term Care Pharmacies;*2013

Sincerely,

B. Douglas Hoey, R.Ph., M.B.A.
Chief Executive Officer

cc: Barbara Edwards, Director, Disabled & Elderly Health Program Group
Joe Fine, Acting Director, Medicaid Pharmacy Division

Attachment 1: Analysis of Costs to Dispense Prescriptions in Independently Owner Long Term Care Pharmacies
Attachment 2: NCPA Analysis of Selected Draft FUL lists vs. NADAC