NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

VIA Electronic Submission

February 10, 2012

Ms. Cindy Mann
Deputy Administrator and Director
Center for Medicaid, CHIP and Survey & Certification
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Subject: Draft Federal Upper Limits (FULs)

Dear Ms. Mann:

On behalf of the National Association of Chain Drugs Stores (NACDS) and its membership, we are providing comments to the draft Federal Upper Limits (FULs) released by the Centers for Medicare & Medicaid Services (CMS) on January 17, 2012.

413 North Lee Street
Alexandria, Virginia
22314

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. Chain pharmacies are the primary providers of prescription medications in both the Medicaid and Medicare Part D programs.

We urge CMS to discontinue publication of draft FUL lists. NACDS has reviewed all four of the draft FUL lists published by the agency, and we have numerous concerns. In addition to the significant reductions in pharmacy reimbursement that would result from implementation of FULs based on Average Manufacturer Price (AMP), we continue to see great variability in FULs from month to month, the tendency of FULs to appear and disappear from draft FUL lists, the lack of correlation between AMP and pharmacy acquisition cost, and the prevalence of FULs that have been calculated in a manner that is inconsistent with the requirements of the Patient Protection and Affordable Care Act (ACA).

In addition, we have begun our analysis of the proposed rule published in the *Federal Register* on February 2, 2012, Medicaid Program; Covered Outpatient Drugs (CMS-2345-P; RIN 0938-AQ41). This rule clearly exemplifies the complexity of expanding the use of AMP from a benchmark for determining manufacturer rebates, to also calculating FULs for pharmacy reimbursement for generic drugs. Based on

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

our initial review, it seems unquestionable that there is no uniformity in the way manufacturers currently are calculating and reporting AMPs. As a result, NACDS believes that the draft FULs, calculated without regulatory guidance and seemingly inaccurate, should neither be made available for nor used as a basis for pharmacy reimbursement. Furthermore, no further draft FUL lists should be published before a final AMP rule is effective. At the completion of rulemaking, CMS should again issue a draft FUL list, subject to the final AMP Rule, for public review and comment.

We base this request on the following key issues:

- AMP is an Inaccurate Benchmark for Pharmacy Reimbursement
- Lack of Consistent AMP Reporting by Manufacturers
- Whether to Calculate a Federal Upper Limit
- Amount of Federal Upper Limit
- Accurate Dispensing Fees are Critical

AMP is an Inaccurate Benchmark for Pharmacy Reimbursement
NACDS continues to have significant concerns with the use of Average Manufacturer Price (AMP) as a basis for pharmacy reimbursement. AMP is not a price paid in the marketplace. Instead, it is a benchmark to determine manufacturer rebates in the Medicaid program.

As part of our comments provided to CMS on October 20, 2011, NACDS attached a list of specific FULs that appear to have been calculated inaccurately, including issues such as calculating FULs using both prescription and over the counter products, inappropriate mixing of products that are not therapeutically equivalent in the same product group, or mismatched package sizes. Despite the fact that this list was provided to CMS almost four months ago, these FULs continue to appear on draft FUL lists, including the most recent draft list issued on January 17, 2012. We have provided a list again as part of our comments and urge CMS to review these materials to ensure only FULs that are calculated according to the requirements of the ACA are included on FUL lists.

Lack of Consistent Reporting by Manufacturers
There are currently no regulations in place to provide guidance to drug manufacturers on how to calculate and report AMP information. The absence of any specific agency guidance or regulation means there is no clear regulatory standard for manufacturers, which leads to great variability in how AMPs are calculated and reported to CMS. In particular, we believe lack of guidance from CMS on bona fide service fees, "5i" drugs, and the adequate documentation/default rule has resulted in inconsistent AMP reporting.

Whether to Calculate a Federal Upper Limit
Because CMS has withdrawn the 2007 AMP rule, including the sections pertaining to the calculation of FULs, there is no regulatory process in place to govern calculation of Federal Upper Limits. As a result, there are significant issues related

to calculating FULs that have not been addressed. Final rulemaking is needed from CMS so FULs are calculated only when three or more therapeutically and pharmaceutically equivalent multiple source drug products (A-rated drug products) are listed in the most current edition of the Food and Drug Administration's Orange Book. These minimum three products must be available for purchase by retail community pharmacies on a nationwide basis. Neither the draft methodology issued by CMS nor the proposed rule describe a process that will accurately or reliably determine if a product is available for purchase by retail community pharmacies on a nationwide basis. This issue of "national availability" is critical, since the AMP of a multiple source drug should not be used to calculate an FUL if it does not meet this requirement.

Amount of Federal Upper Limit

The Affordable Care Act provides CMS with the authority to calculate Federal Upper Limits at "no less than" 175 percent. The "no less than" language in the ACA is critical. While Congress created a floor of 175 percent for calculating FULs, it clearly recognized that CMS would require flexibility in the level of multiplier in order to maintain patient access to prescription medications.

Congress did not limit the ability of CMS to increase the multiplier to calculate FULs, but rather provided broad authority. Based on analysis of the draft FUL list, it appears that at least initially, CMS may need to increase the multiplier for calculating all FULs. If FULs begin to more closely approximate acquisition cost over time, there still may be cases where a higher multiplier should be used. These instances include:

- When FULs are below a state AAC benchmark, or the National Average Drug Acquisition Cost (NADAC) benchmark to be collected by CMS;
- If AMP is below Average Sales Price (ASP);
- If states fail to increase dispensing fees to reflect the cost to dispense medications to Medicaid patients;
- In situations where AMPs plummet from month to month as a result of discounts being applied or other issues; and
- If FULs are calculated for inhalation, infusion, instilled, implanted, or injectable drugs.

Accurate Dispensing Fees are Critical

There are multiple components of pharmacy reimbursement – reimbursement for drug product, reimbursement for the cost of dispensing a prescription drug to a Medicaid patient, and reimbursement for professional services, such as medication therapy management (MTM) and immunizations.

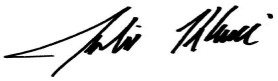
In order to ensure that pharmacies are not reimbursed below the cost to acquire and dispense prescription medications to Medicaid patients, CMS should make clear to states that in order to maintain patient access to pharmacies, dispensing fees must be reviewed and adjusted to reflect no less than the true cost of dispensing prescription medications to Medicaid patients. Further, CMS should advise states that the draft FULs issued by the agency on September 22, 2011, October 21, 2011, November 19, 2011, January 17, 2012 and any future draft FUL lists, are for public review and comment, and are not to be used for pharmacy reimbursement.

The importance of an accurate dispensing fee was frequently raised in the context of AMP-based FULs. Congress and the Congressional Budget Office (CBO), as well as CMS, made clear that use of AMP to calculate FULs would require a corresponding adjustment in dispensing fees. NACDS strongly urges CMS to provide clear guidance to states on the need to adjust dispensing fees before the use of AMP-based FULs.

Conclusion

Thank you again for the opportunity to share our views on the draft FUL list. We look forward to continuing to work with you to improve the accuracy and reliability of AMP-based FULs. We urge CMS to complete formal rulemaking with an opportunity for public comment before implementing the pharmacy reimbursement provisions of the Affordable Care Act.

Sincerely,



Julie Khani
Vice President, Public Policy

cc: Penny Thompson, Deputy Director, Center for Medicaid and CHIP Services
Larry Reed, Director, Division of Pharmacy