



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



Via Electronic Submission

July 12, 2013

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

Re: Draft Three-Month Rolling Average Federal Upper Limits (FULs)

Dear Ms. Mann:

On behalf of the National Association of Chain Drugs Stores (NACDS), the National Community Pharmacists Association (NCPA) and our membership, we are providing comments to the draft three-month rolling average Federal Upper Limits (FULs) released by the Centers for Medicare & Medicaid Services (CMS) on July 1, 2013.

NACDS and NCPA represent the totality of retail community pharmacies - chain and independent pharmacies, supermarket and mass merchant pharmacies. Our members are deeply committed to the patients we serve, and in particular, Medicaid patients often rely heavily on their local pharmacy. We appreciate the thoughtful approach CMS has adopted thus far in the implementation of the Medicaid pharmacy reimbursement provisions of the Affordable Care Act (ACA). Due to the complexities associated with the calculation of Average Manufacturer Price (AMP), as well as the dramatic changes involved in shifting to a new reimbursement benchmark, our organizations urge the agency to wait until final rulemaking is effective before AMP-based Federal Upper Limits (FULs) are used for pharmacy reimbursement.

Concerns with Draft Three-Month Rolling Average Federal Upper Limits

NACDS and NCPA have reviewed all of the draft FUL lists published by CMS, including the draft three-month rolling average FUL list, and we continue to have numerous concerns with the use of average manufacturer price (AMP) as a pharmacy reimbursement benchmark. In addition to the significant reductions in pharmacy reimbursement that would result from implementation of FULs based on 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 Affordable Care Act (ACA).

Due to the volatility of AMPs, we are appreciative of the efforts by CMS to calculate FULs based on a three-month rolling average of AMP and encourage the use of a twelve-month rolling average to calculate FULs, as a means to provide further smoothing and reduce variability. We believe the additional smoothing provided by calculations based on a rolling average would reduce variability from month to month, providing greater predictability. This predictability is important for all pharmacies, but particularly those that serve a high percentage of Medicaid patients.

Slide eleven from the CMS Webinar of December 5th states, “We are suggesting that states can use the draft monthly AMP-based FUL, or the draft three-month rolling average FUL, once they are finalized, depending on the approved state plan, to develop a pharmacy reimbursement methodology that will allow their pharmacy payments to remain within the FUL in the aggregate.” NACDS and NCPA advocate for the use of a rolling average to calculate Federal Upper Limits. However, CMS appears to be suggesting that multiple FUL lists would be calculated each month, using different factors, and states could select an FUL list to be used for pharmacy reimbursement, as long as total pharmacy reimbursement “remain within the FUL in the aggregate.” Based on the CMS slides, it is unclear which FUL list will be used to determine if pharmacy payments remain below FULs in the aggregate. For example, if a state uses an FUL list calculated with a three-month rolling average for pharmacy reimbursement, will the three-month rolling average FUL list also be used to determine if payments were below the FUL in the aggregate? If CMS elects to calculate and publish multiple FULs lists, additional clarity around the use of FUL lists will be necessary.

In addition, NACDS and NCPA are concerned about FULs on the draft lists that have the potential to be applied incorrectly. We have previously identified 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. CMS has identified and corrected some of these cases. We urge CMS to continue to make changes to the draft FUL lists in this regard. In the future, when there are products that are not therapeutically equivalent, NACDS and NCPA recommend separate AMP-based FULs be published by NDC so that FULs will be applied correctly.

Lack of Correlation among Benchmarks

NACDS and NCPA are greatly concerned with the lack of correlation among NADAC, AMP-based FULs, and NARP, and the confusion this will likely cause in the marketplace.

While AMP is meant to be the price paid to manufacturers by retail community pharmacies and by wholesalers for drugs distributed to retail community pharmacies, and NADAC is supposedly the price paid by pharmacies to acquire drugs from manufacturers and wholesalers, the two benchmarks are not strongly correlated. In fact, they frequently diverge by significant amounts. Although the use of a three-month rolling average reduces the variance, there is still a lack of correlation. For example, when comparing the August 2012 AMP-based FULs with corresponding products from the November 1, 2012 NADAC file, a large number of FULs were found to be lower than the lowest published NADAC for each

corresponding product group. For March 2013 FUL groups, a total of 44.7% had a published FUL that was lower than the published NADAC for that group. Additionally, 22.3% of products had a FUL value set below ingredient purchase cost (AAC) and 10% of all products had a NADAC value set below AAC.

The way in which FUL, NADAC and NARP data are calculated and presented will result in additional confusion. FULs and NADACs are calculated and published at the unit level (i.e. per pill) and include drug product costs only. In contrast, NARP is calculated and published at the most commonly dispensed level (i.e. 30-day supply) and includes pharmacy dispensing fees and patient cost sharing. The very nature of the way in which the benchmarks are calculated makes it impossible for them to be used as any type of comparison tool. We urge CMS to include a prominently displayed explanation of the NARP data on its website, explaining the differences among AMPs, FULs, NARPs and NADACs.

Comprehensive Pharmacy Reimbursement

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 other professional services, such as medication therapy management and immunizations.

We applaud CMS for its actions to ensure that states that move to a benchmark based on pharmacy acquisition costs base total pharmacy reimbursement on comprehensive dispensing fee studies. This has been critical to ensuring that pharmacies are not reimbursed below the cost to acquire and dispense prescription medications to Medicaid patients. We believe a similar policy is needed in the case of AMP-based FULs. We urge CMS to 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.

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 community 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.

Conclusion

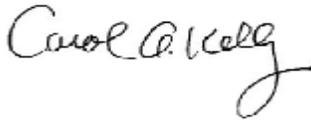
There continues to remain hundreds of drugs where the FULs are lower than the current market-based acquisition costs for community pharmacies. If the draft sets of FULs are implemented, it could result in the loss of access to community pharmacies for Medicaid patients. This could result in negative 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 previous letters sent to you regarding the draft FUL lists, we continue to believe strongly 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. We urge the final regulation be published as soon as possible so that all affected parties can better understand how AMP-based reimbursement will affect them.

Thank you for the opportunity to share our views on the draft three-month rolling average FULs. We look forward to continuing to work with you to improve the accuracy and reliability of these benchmarks.

Sincerely,



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