National Community Pharmacists Association: Concerns Regarding Proposed Rule: Medicaid Covered Outpatient Drugs

October 5, 2015

Lack of Clarity on Effect of Proposed Rule on Small Retail Pharmacies

- Proposed Rule: "At this time, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. We request any information that may help us better assess those effects before we make final decisions."

NCPA Membership Demographics

- Pharmacy owners, managers and employees of more than 22,000 independent community pharmacies across the United States
- Often located in underserved rural and urban areas that serve Medicaid beneficiaries
- Independent pharmacies represent 52% of all rural pharmacies
- Over 1,800 independent community pharmacies operating as the only retail pharmacy in their rural communities

Independent Community Pharmacies and Medicaid

- For the average independent community pharmacy, 93% of all revenues are derived from prescription drug sales
- In comparison: a typical chain pharmacy derives about 67% of all revenues from prescription sales and the remainder from "front-end" retail items
- For the average independent community pharmacy, about 17% of all prescription revenue is derived from Medicaid (percentage is much higher in urban and rural areas)
- In comparison: for the average chain pharmacy, about 7% of all prescription revenue is derived from Medicaid

National Rural Health Association Policy Brief on Pharmacy http://www.nrharural.org]

- Key Findings
- Rural pharmacies are unlikely to generate enough sales on non-prescription items to offset any losses from prescription sales
- Reality of rural retail pharmacy practice: medications cannot be purchased at discounted prices available to large retail chains and lower population densities may not generate sales volume necessary to cover operational expenses.

National Rural Health Policy Brief on Pharmacy

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- Key Recommendations:
- *Fair payment rates for Medicare and Medicaid high enough to ensure the ongoing presence of pharmacy care providers—To minimize impact on the federal budget, such a policy could be targeted towards a subset of pharmacies identified as essential for local access*

- Monitor financial health of pharmacies with higher than proportionate share of Medicaid prescriptions and those in rural or low-income areas. Once closed, pharmacies are difficult to re-open. It is critical to avoid the loss of pharmacies identified as critical access points

NCPA and Medicaid

- Medicaid is not "marginal" business to the average independent pharmacy
- Continual expansion of Medicaid will only increase the amount of Medicaid patients that present at the pharmacy

Continued Concerns With Volatility of Draft FULs

- Wide range of variability in how each individual manufacturer reports AMP
- Mis-aligned incentives at work by using a single metric upon which to base manufacturer-owed Medicaid rebates and pharmacy reimbursement
- Manufacturers are incentivized to report low-to minimize the amount of rebate $ owed (especially on generics)
- Pharmacy reimbursement is therefore based upon an artificially low number

Draft FUL List Observations

- Draft FUL lists have been published Since September 2011 to date (approx. 30-40 total)
- Since the beginning of the publication of the draft FUL lists, 47% of the products on these lists have had FUL values lower than the market-based acquisition costs (NADAC)
- Throughout all of the FUL lists released thus far, the percentage of products with FULs below acquisition cost is somewhat constant [BUT NOT ALWAYS THE SAME PRODUCTS]
- Draft FULs are more volatile month-to-month compared to NADAC
- In instances in which the FUL for a product is below the NADAC, it is usually significantly lower
- In comparison, in instances in which the FUL for a product is above the NADAC, it is usually only slightly higher

2012 OIG Report [OEI-03-11-00650
Recommended Implementation of FULs Based on Survey
However: Survey sample non-representative and not statistically valid

- Report: FULs exceed "sampled" pharmacy acquisition costs (not NADAC) by 43% in the aggregate

- Out of a total of 58, 545 pharmacies in the U.S., the survey solicited information from just 120 pharmacies.

- Sampling not representative and therefore not statistically 117 responses received

- Study finding do not take into account most states' "lower of" methodologies and that most dispensing fees are a fraction of the true cost to dispense

Regulatory Flexibility Act (RFA)

- Requires agencies to analyze options for regulatory relief for small entities if a rule has a significant impact on substantial number of small entities

- Proposed rule found to impact *small retail community pharmacies*, small manufacturers and small MCOs

Independent Community Pharmacies Disproportionally Affected by Proposed Rule

- Virtually all revenue of independent community pharmacies is derived from prescription sales
- In an average independent pharmacy: 17% of prescriptions are Medicaid; Percentage can be much higher
- Independent pharmacies tend to be located in very rural or urban areas with large concentrations of Medicaid recipients
- Independent pharmacies are not able to purchase generics directly from manufacturer (as are chains); Must go through a wholesaler
- Acquisition costs are often at least 25% to 50% higher than those of publicly-held chain pharmacies

Secretary Has Flexibility to Allow Higher FULs in Certain Circumstances

- Statute requires that CMS set the FUL at "NO LESS THAN" 175% of the weighted average AMP
- Secretary could allow higher FULs for:

➢ Independent small business community pharmacies

➢ Short supply drugs w/sudden price spikes

➢ 5i drugs

➢ To allow the FUL to correspond to NADAC

OIG Report Finds That Multiplier Higher Than 175% Needed for Independent Pharmacies

- *Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices* [October 2011, A-06-11-00002]

- For multiple-source drugs with a FUL, the acquisition costs of rural independent pharmacies are 249% of AMP, while for urban independent pharmacies they are 240%

- For multiple-source generic drugs without an FUL, acquisition costs of rural independent pharmacy are 221% of AMP, while urban independent pharmacies they are 203%

Transition Period for Implementation Needed

- Transition period of one year requested: Time for states to complete necessary legislative/regulatory changes and system upgrades [Manufacturers also need time to upgrade systems and alter AMP methodologies]

- November 2013 memo, CMS recommends that as states shift their Medicaid reimbursement methodologies, they evaluate the adequacy of current dispensing fee

- Most states will need to file a State Plan Amendment (SPA) with CMS prior to implementing new methodology

Guidance to States Needed Upon Release of FULs

- AMP-FULs should be used only in aggregate and not on a drug by drug basis in any state "lower of" reimbursement or in a State's Maximum Allowable Cost (MAC) list

- CMS Statement Needed Clarifying that if NADAC is used; state does not have to affirmatively prove that total expenditure on generics is below FULs considered in aggregate (State presumed to be in compliance with statute)

- CMS Statement needed emphasizing critical importance of adequate dispensing fee [With either AMP-based FULS OR NADAC]

Thank You

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