Model N
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EXECUTIVE BRIEF

PHARMA

Critical Issues for the Pending AMP Ruling

INTRODUCTION

On Friday, January 27, 2012, the Centers for Medicare & Medicaid Services (CMS) published a Proposed Rule in the Federal Register (RIN# 0938-AQ41) to implement the Medicaid Drug Rebate Program (MDRP) provisions of the Patient Protection and Affordable Care Act (ACA). While the scope of the ruling is wide-ranging and provides manufacturers with a greater understanding of CMS's position on critical concerns, it also does not answer many questions and will, in all likelihood, have a significant impact on manufacturers' rebate liabilities and the cost of compliance. It is important to note that the CMS does not mention anything about retroactive applicability of any conditions in the proposed rule.

The Final Rule was expected to be released in 2012, then early 2013, then August of 2013. Now it is expected in January of 2014. The ACA provisions impact the MDRP in a number of areas including the Average Manufacturers Price (AMP) calculations, Best Price (BP) calculations, and Unit Rebate Amount (URA) calculations. These areas are the basis for Medicaid rebates payable by manufacturers. Once the final ruling arrives, companies will need to quickly update their GP systems to bring them into compliance with the new formulas.

THE TOP 5 PENDING CHANGES

1. The AMP "presumed inclusion" was rejected and manufacturers are expected to trace sales to RCPs.

WHAT DOES THIS MEAN TO YOU?

The need to identify the end customers of retail community pharmacies means manufacturers will be required to develop infrastructure and new data collection processes and significantly change the relationship they have with wholesalers.

2. Non-5i drugs not distributed through RCPs are given a new category of eligible purchasers.

WHAT DOES THIS MEAN TO YOU?

The specific non-5i drugs have not been defined, nor has who exactly the non-RCP entities are. Even so, manufacturers will be required to categorize the purchasing entities to permit the calculation of AMP for these drugs.

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TOP 5 CHANGES (CONT.)

3. 5i "not generally dispensed" status proposed to be continually reassessed by manufacturers.

WHAT DOES THIS MEAN TO YOU?

This will require new administrative process(es) and would be an added compliance risk. Also validating and changing on a monthly/quarterly basis would cause the AMP to vary greatly and make the additional rebate comparison to base date AMP variable highly erratic.

4. CMS proposes to expand the Rebate Program to include the U.S. territories – both for rebates and for calculations.

WHAT DOES THIS MEAN TO YOU?

Manufactures will need to include Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa in their definitions of "States" and "United States." Adding these new territories will require new policies, procedures, additional headcount, and training programs in order to cope with these changes.

5. Referral to the OIG and significant civil money penalties are proposed for late filers.

WHAT DOES THIS MEAN TO YOU?

If a Manufacturer does not submit monthly AMP, monthly AMP units, quarterly AMP or quarterly Best Price within the 30-day reporting window, CMS will report them to the OIG and will subject late filers to civil money penalties of $10,000 per day per drug.

CONCLUSION

These changes will have a significant impact on Manufacturers in terms of additional infrastructure, administrative burdens, and compliance risk. We believe the current Model N platform, by design, will be able to deal with the majority of the changes. Additional enhancements will be expedited to allow the platform to meet the challenges of the final rule. Model N is committed to providing you with timely updates that keep you in compliance and ensures that your partnership with Model N helps you to stay ahead of the game.

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