

CMS Proposes Major Changes to AMP Rule

The Proposed Rule provides provisions that will significantly impact pharmaceutical manufacturers' rebate liability, price reporting calculations, and possibly their operations.

February 6, 2012

For those pharmaceutical manufacturers that expected the long-awaited average manufacturer price (AMP) proposed rule to be replete with provisions that significantly impact their rebate liability, price reporting calculations, and possibly their operations as well, the proposed rule does not disappoint. The Centers for Medicare & Medicaid Services (CMS) published its proposed rule (the Proposed Rule) in the *Federal Register* on February 2. The overarching purpose of the Proposed Rule was to promulgate regulations implementing Medicaid Drug Rebate Program (MDRP) provisions in the Affordable Care Act, which to a large extent overrode CMS's AMP regulation, which it promulgated pursuant to the Deficit Reduction Act (DRA) and withdrew in part last year. However, the Proposed Rule exceeds that mandate, revises portions of the DRA rule it did not withdraw, and tackles other subjects as well, such as extending the Medicaid Drug Rebate Program to U.S. territories. As such, the Proposed Rule is both complex and broad.

[We've prepared a chart summarizing the provisions of the Proposed Rule.](#)¹ However, this summary focuses only on those issues that are likely to have the most serious program implications, and does not include every ramification of each proposal. Individual manufacturers may also find a significant number of individual changes that affect their particular business model, as well as issues not addressed in this summary. Accordingly, it may be beneficial for each manufacturer to do a more thorough review than is provided here.

Comments are due on April 2.

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1. The chart is also available at http://www.morganlewis.com/pubs/FDA_Chart_SummaryProposedAMPRegulation_06feb12.pdf.

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