



September 3, 2010

CMS Proposes to Withdraw AMP, FUL and Multiple Source Drug Regulations

On September 3, 2010, the Centers for Medicare & Medicaid Services (CMS) published a [proposed rule](#) to withdraw existing regulations regarding the determination of average manufacturer price (AMP), the establishment of Federal upper limits and the definition of multiple source drug. In their place, CMS proposes to require manufacturers to rely on the new statutory definitions of AMP, wholesaler, and retail community pharmacy until new interpretive regulations are promulgated.

The proposed rule does not include any substantive guidance interpreting the new statutory definitions and does not express any of the agency's thinking on how manufacturers should calculate AMP going forward.

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Specifically, CMS intends to:

- delete the AMP definition at 42 C.F.R. § 447.504;
- delete the definition of "multiple source drug" at 42 C.F.R. § 447.504;
- delete the FUL requirements at 42 C.F.R. § 447.514; and
- make certain conforming amendments as necessary.

The proposed rule has a 30 day public comment period which will close on Monday, October 4, 2010.

Implications for Manufacturers of Pharmaceuticals and Biologics

In the preamble to the proposed rule, CMS expressly advises drug manufacturers to base their AMP calculations (presumably for periods after October 1) on the definitions set forth in revised section 1927 of the Act and to disregard the AMP and AMP-related definitions provided in existing regulations and guidance. In light of the lack of regulatory guidance, this means that manufacturers must be prepared to calculate their October monthly AMPs (due November 30) through their own interpretations of the statutory definitions. This task is complicated by the lack of specificity or



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clarity in the new law (including the definition of what constitutes a “retail community pharmacy” and with regard to the newly created “5i” AMP). King & Spalding is prepared to assist companies in the development of reasonable assumptions that best effectuate the statutory scheme.

CMS signaled in conforming amendments that it will provide for the restatement of base date AMP consistent with the terms of the new statutory definitions. Unfortunately, the Agency did not say when such restatements would need to be submitted to CMS.

While this proposed rule leaves unanswered the industry’s pressing questions regarding how to interpret many of the provisions included in the health care reform laws, we anticipate that additional regulations and guidance documents defining AMP and implementing changes to the 340B program will be released soon. This guidance may not be released until after the October 1, 2010, effective date for the new AMP definition, however. If you have questions regarding this proposed rule, the transition to AMP under the new laws, or need any other information related to government price reporting, please call a member of our team.

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