

This Week's ML Strategies Health Care Update: Big Changes (Possibly) Ahead for Drug Manufacturers

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On Monday, **ML Strategies** (MLS) posted its weekly **Health Care Update**, which provides information from the previous week on a variety of important health care-related topics like implementation of the Affordable Care Act, Congressional initiatives affecting the health care industry, and state and federal health regulatory developments.

In this week's Update, MLS highlights two major developments for prescription drug manufacturers (among other topics):

1. the Medicaid Outpatient Drug Rule went to the White House's Office of Management and Budget for final review; and
2. a federal district court judge ruled in *Amarin Pharma, Inc. v. FDA* that a drug manufacturer could market to health care professionals off-label uses for a prescription drug provided the manufacturer's statements were truthful and non-misleading.

The Medicaid Outpatient Drug Rule could set standards for the Medicaid Drug Rebate Program and also provides for significant changes to what is and is not included in the Average Manufacturer Price (AMP) calculation, as well as how "best price" would be calculated for rebates. Modifying the AMP calculation for the Medicaid program appears to be a priority for Congress, as the House also expressed interest in this issue when it passed the 21st Century Cures Act.

The *Amarin Pharma* decision is another significant victory for the drug industry (following the 2012 *United States v. Caronia* decision that drug manufacturers should be allowed to share and discuss with providers materials that support off-label claims). Industry stakeholders must now wait to see how the FDA will react to *Amarin Pharma* and whether it will apply the decision in its off-label oversight framework.

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