


THE FINAL RULE

6 KEY AREAS OF COMPLIANCE FOCUS

The Centers for Medicare & Medicaid Services (CMS) issued the Covered Outpatient Drugs Final Rule in January 2016.

For compliance officers, the Final Rule's impact will be felt in a variety of areas—but there are specific aspects that should remain top of mind.

 You can also hear more from Huron on this issue by following @Huron for up-to-date webinar, events, and speaking engagements.



Bona fide service fees and fair market value

The Final Rule reinforces the importance of understanding both.



Bundling arrangements

An organization's bundling agreements can impact statutory pricing, among other important pricing aspects.



Extension of Medicaid to Puerto Rico and U.S. territories

The expansion entails a wide array of challenges across an organization, including contracting relationships and pricing.



Authorized generics relationships

This can significantly impact Medicaid Average Manufacturer Price (AMP) calculations, as well as an indirect Public Health Services program (PHS) pricing impact.



Patient assistance programs and coupons

These programs need to meet the criteria for an excludable program under the new CMS guidance.



Specialty pharmacy

Manufacturers now need to accurately determine whether its specialty pharmacy customers are retail community pharmacies (RCP).

For more information about compliance implications of the AMP's Final Rule, you can contact Huron by visiting our **Final Rule landing page** at www.huronconsultinggroup.com/AMPFinalRule.

