Health Services Provider's Settlement with DOJ Includes Detailed Factual Admissions and Agreement to Cooperate Against Co-Defendant Pharmaceutical Company

On January 8, 2014, pharmaceutical provider BioScrip, Inc. (BioScrip) reached a settlement with the Department of Justice (DOJ) to resolve claims under the False Claims Act (FCA) and the Anti-Kickback Statute (AKS), stemming from an alleged multi-million-dollar health care fraud involving the drug Exjade. In connection with the settlement – which requires BioScrip to pay $11.69 million to the federal government and $3.31 million to settle related state claims – BioScrip made extensive factual admissions and agreed to cooperate with the DOJ against other entities and individuals, including co-defendant Novartis Pharmaceuticals Corp. (Novartis). While settling with BioScrip, the DOJ simultaneously filed an amended complaint against Novartis, which includes further FCA and AKS claims. The settlement and amended complaint were filed in the United States District Court for the Southern District of New York (SDNY).

The settlement is unusual in a number of ways. First, it is in the form of a court order and stipulation of dismissal rather than a simple contract between government stakeholders and the settling defendant. Second, it contains extensive factual admissions, which typically have not been required from health care companies as part of their resolution of what are often highly contested theories of potential civil liability in FCA-driven investigations. Indeed, most settlement agreements contain explicit denials of the government's allegations by the defendant. Third, the stipulation and order of dismissal includes the requirement that the company cooperate with the government in its pursuit of claims against others. This last concession is the most unusual – typically such a term would be found, if at all, within the context of the resolution of a criminal matter.

While the SDNY United States Attorney's Office (USAO) has recently required factual admissions in connection with certain civil FCA settlements – something companies prefer to avoid in light of the potential collateral consequences in other enforcement proceedings or private litigation – it is too early to draw conclusions about whether this is part of a broader shift in the government's approach to settling civil matters. However, the question is worth asking. In June 2013, the Securities and Exchange Commission (SEC) announced a change to its long-standing policy of allowing respondents in civil enforcement actions to "neither admit nor deny" the SEC's factual allegations when resolving their claims. Under the revised policy, the SEC will require certain respondents to admit wrongdoing as a condition of settling enforcement cases. While the BioScrip settlement and the SDNY USAO's experiment with new forms of civil resolution remain outside the norm, observers in the health care arena and beyond will closely watch whether this unusual settlement proves to be a rare occurrence.

We will continue to monitor developments in this area. If you have any questions or would like to discuss the foregoing or any related matter, please contact the Ropes & Gray attorney with whom you regularly work or an attorney in our false claims act practice.