

Dorsey Alert: HHS Regulatory Sprint May Impact FCA Enforcement Trends

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The False Claims Act (“FCA”) is an ever-present concern among health care providers and counsel, which is why it is no surprise that the Department of Health and Human Services’ (HHS) recent “Regulatory Sprint to Coordinated Care” may impact FCA enforcement trends. Dorsey’s Health Law Blog team has been closely monitoring the “Regulatory Sprint,” including the sweeping set of proposed regulations issued by the HHS Office of Inspector General (“OIG”) and Centers for Medicare & Medicaid Services (“CMS”) that introduce significant new value-based terminology, safe harbors and exceptions to the federal anti-kickback statute (“AKS”) and federal physician self-referral law (“Stark Law”), respectively.

These developments are of note for potential FCA enforcement trends, particularly because the AKS provides that a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Further, the federal government and *qui tam* relators are increasingly pursuing alleged violations of the Stark Law under the FCA, based on arguments, for example, that claims submitted in violation of the Stark Law are false claims for FCA purposes. The new proposed AKS safe harbors and Stark exceptions and policy clarifications from the agencies that are intended to ease compliance burdens may potentially lead to fewer alleged violations of non-compliance with these laws, and thus fewer FCA actions based on non-compliance with them.

To read more about the Regulatory Sprint, Dorsey’s FCA Now blog is pleased to refer you to Dorsey’s [Health Law Blog landing page](#) for an overview and link to further resources.

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