

A Massive Number of New Health Law Regulatory Proposals as Part of the “Regulatory Sprint to Coordinated Care”: Proposed Changes to the Stark Law, Anti-Kickback Statute, Beneficiary Inducement CMP, Privacy Laws Governing Substance Use Disorder Records, and the Stark Law Advisory Opinion Process

October 9, 2019 – *Dorsey Health Law*
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Today, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) each released their long-anticipated proposed rules to revise the federal self-referral law (or “Stark Law”) regulations, the safe harbors under the federal anti-kickback statute (AKS), and the civil monetary penalty law (CMP) for beneficiary inducements. The proposed rules are part of HHS’s “Regulatory Sprint to Coordinated Care,” which seeks to remove regulatory obstacles to care

coordination and a value-based healthcare delivery system.

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Relatedly, the Substance Abuse and Mental Health Services Administration (SAMHSA) published proposed rules to revise privacy rules for substance use disorder records on August 26, and CMS published proposed rules to revise the Stark Law advisory opinion regulations on August 14 (as part of the Medicare Physician Fee Schedule proposed rule).



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