

and OIG. **To help you digest these materials, a team of attorneys from Dorsey & Whitney’s Healthcare Transactions and Regulations Practice Group has published two white papers, which are available at the links below. In addition, we have posted at a link below the playback of a webinar we hosted about the final rules on January 6, 2021.** The white papers and webinar playback provide an in-depth summary of the changes to these regulations, including key provisions from CMS and OIG preamble guidance. Finally, we have posted below redlines comparing the existing Stark Law, AKS and CMPL regulations to the revised version of each of these regulations in the final rules.

With respect to health information privacy, the HHS Office for Civil Rights (“OCR”) issued a Notice of Proposed Rulemaking (“[NPRM](#)”) on December 10, 2020 which proposes changes to the Health Insurance Portability and Accountability Act (“HIPAA”) and to the Health Information Technology for Economic and Clinical Health Act (“HITECH”) Privacy Rule. Additionally, the HHS Substance Abuse and Mental Health Services Administration (“SAMHSA”) [published final rules to revise regulations related to the privacy of substance use disorder treatment records](#) in July 2020.

These changes in federal regulations are anticipated to make a significant impact on healthcare providers and other stakeholders that may have been reticent to initiate certain care coordination arrangements because of perceived regulatory barriers and lack of regulatory clarity. In addition, clarifications to existing regulations impact stakeholders beyond their involvement in care coordination arrangements.

The team of attorneys in Dorsey & Whitney’s Healthcare Transactions and Regulations Practice Group will continue to closely monitor these changes, and post updates and analysis below as new information becomes available.

[Stark Regulatory Changes Effective January 1, 2022 Require Modifying Certain Group Practice Compensation Methodologies | News & Resources](#)

[Webinar Playback: Final Stark and Anti-Kickback Statute Rules: What You Need to Know](#)

[White Paper: Understanding the Final Rules to Revise the Stark Law Regulations](#)

[White Paper: Understanding the Final Rules to Revise the Anti-Kickback Statute and Beneficiary Inducement Civil Monetary Penalty Regulations](#)

[The Regulatory Sprint Catches up to HIPAA: New Proposed HIPAA Rules](#)

[Redline of Final AKS Regulatory Text](#)

[Redline of Final CMP Regulatory Text](#)

Redline of Final Stark Regulatory Text effective 1.1.2022 - 411.352(i) only

Redline of Final Stark Regulatory Text effective 1.19.2021

Much-Anticipated Final Rules to Revise Stark Law, Anti-Kickback Statute, Beneficiary Inducement CMP Regulations Released under "Regulatory Sprint to Coordinated Care"

CMS Finalizes Changes to the Stark Advisory Opinion Regulations; 2020 DHS Code List and CPI-U Updates

Sweeping Proposals Issued by CMS to Revise Stark Law Regulations

Sweeping Proposals Issued By OIG To Make Changes To The Anti-Kickback Statute Safe Harbors And Add An Exception To The Civil Monetary Penalty Law Governing Beneficiary Inducements

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

CMS "Actively Working" on Stark Law Reforms to be Issued Later this Year; "Regulatory Sprint to Coordinated Care" Continues

OIG Seeks Public Input on Anti-Kickback Statute and Beneficiary Inducements CMP as part of the "Regulatory Sprint to Coordinated Care"

Calls for Modernizing the Stark Law Continue; CMS Seeks Public Input on Stark Law Reforms