

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

March 18, 2019 – Dorsey Health Law
by Alissa Smith and Laura B. Morgan

The Centers for Medicare & Medicaid Services (CMS) is "actively working" on updates to regulations under the federal physician self-referral law (or "Stark Law"), according to CMS Administrator Seema Verma during a March 4, 2019 [speech](#). Verma stated that the updated regulations will be issued later this year, and "will represent the most significant changes to the Stark law since its inception."

Verma explained in her remarks that the Stark Law, when enacted in 1989, made sense in a fee-for-service context, but as health care transitions to a value-based system where providers take on risk and payment is for outcomes rather than individual services, "we don't have nearly as much need to interfere with who's getting paid for what service." According to Verma, CMS hopes that Stark Law regulatory changes "will help spur better care coordination and help support our work to remove barriers to innovation while continuing to provide appropriate safeguards for our programs." Verma stated that the updated regulations will include "clarifying the regulatory definitions of volume or value, commercial reasonableness and fair market value; addressing issues such as lack of signature, incorrect dates or other areas of technical noncompliance; and updating the regulation to address a world in which there are cybersecurity and electronic health records requirements."



These Stark Law regulatory reforms are part of the "Regulatory Sprint to Coordinated Care" launched by the Department of Health and Human Services (HHS). Under this initiative, various HHS agencies have issued requests for information (RFIs) to solicit feedback from stakeholders on removing regulatory obstacles to care coordination. CMS published an [RFI](#) on June 25, 2018 soliciting comments regarding Stark Law reforms (as we described in our post [here](#)), which received [392 comments](#) before the close of the

Related People

- Alissa Smith

Related Capabilities

- Healthcare & Life Sciences
- Healthcare Transactions & Regulations
- Healthcare Litigation
- Medical Devices

comment period. We anticipate that CMS will summarize and respond to many of the comments that it received in preamble to the proposed Stark Law regulations to be issued later this year, as well as incorporate suggestions from stakeholders in the proposed regulations themselves.

Also as part of the Regulatory Sprint, the HHS Office of Inspector General (OIG) published an [RFI](#) on August 27, 2018 soliciting comments on reforms to the anti-kickback statute and beneficiary inducements civil monetary penalty (as we described in our post [here](#)), which received [359 comments](#) before the close of the comment period. Additionally, the HHS Office for Civil Rights (OCR) published an [RFI](#) on December 14, 2018 soliciting comments on reforms to the Health Insurance Portability and Accountability Act (HIPAA) privacy and security regulations, on which the comment period closed last month. The fourth and final area of focus of the Regulatory Sprint (according to an HHS [press release](#)) is 42 CFR Part 2, which relates to the confidentiality of substance use disorder patient records. An RFI under the Regulatory Sprint for this regulation has not been published by the Substance Abuse and Mental Health Services Administration (SAMHSA, which is the agency that administers this regulation). We will provide information about regulatory reform developments under these other areas of the Regulatory Sprint as they become available.