

FOR IMMEDIATE RELEASE**October 9, 2019****Contact: HHS Press Office****202-690-6343****media@hhs.gov**

HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care

Today, the Department of Health and Human Services (HHS) announced proposed changes to modernize and clarify the regulations that interpret the Physician Self-Referral Law (the “Stark Law”) and the Federal Anti-Kickback Statute.

The proposed rules provide greater certainty for healthcare providers participating in value-based arrangements and providing coordinated care for patients. The proposals would ease the compliance burden for healthcare providers across the industry, while maintaining strong safeguards to protect patients and programs from fraud and abuse.

The proposed rules are part of HHS’s Regulatory Sprint to Coordinated Care, which seeks to promote value-based care by examining federal regulations that impede efforts among providers to better coordinate care for patients.

“President Trump has promised American patients a healthcare system with affordable, personalized care, a system that puts you in control, provides peace of mind, and treats you like a human being, not a number. But too often, government regulations have stood in the way of delivering that kind of care,” said HHS Secretary Alex Azar. “Regulatory reform has been a key piece of President Trump’s agenda not just for faster innovation and economic growth, but also better, higher-value healthcare. Our proposed rules would be an unprecedented opportunity for providers to work together to deliver the kind of high-value, coordinated care that patients deserve.”

“These proposed rules would be a historic reform of how healthcare is regulated in America,” said HHS Deputy Secretary Eric Hargan. “They are part of a much broader effort to update, reform, and cut back our regulations to allow innovation toward a more affordable, higher quality, value-based healthcare system, while maintaining the important protections patients need. Here at HHS, CMS and the Office of Inspector General recognized the need for reform and have acted to produce serious and thoughtful sets of proposals.”

The Stark Law’s new value-based exceptions, under the proposed rule issued by the Centers for Medicare & Medicaid Services (CMS), acknowledge that incentives are different in a healthcare system that pays for value, rather than the volume, of services provided. They include proper safeguards that

ensure the Stark Law will continue to provide meaningful protection against overutilization and other harms, while giving physicians and other healthcare providers added flexibility to improve the quality of care for their patients.

“We serve patients poorly when government regulations gather dust in the attic: they become ever more stale and liable to wreak havoc throughout the healthcare system,” said CMS Administrator Seema Verma. “Administrative costs are driving up the cost of healthcare in America – to the tune of hundreds of billions of dollars. The Stark proposed rule is an important next step in President Trump’s healthcare agenda for Americans. We are updating our antiquated regulations to decrease burden for providers and helping bring down these increasingly escalating costs.”

The proposed changes to the regulations related to the Federal Anti-Kickback Statute and the Civil Monetary Penalties Law issued by the Office of Inspector General (OIG) would, if finalized, address the longstanding concern these laws unnecessarily limit the ways in which healthcare providers can coordinate care for patients. The changes would offer flexibility for beneficial innovation and improved coordinated care through, for example, outcome-based payment arrangements that reward improvements in patient health. The changes would also make it easier for physicians and other healthcare providers to ensure they are complying with the law by offering specific safe harbors for these arrangements.

“Any patient can tell you how difficult it is to coordinate their own care. This proposed rule would help patients to focus on their health, enable providers to better coordinate high-quality healthcare, and empower both to achieve improved health outcomes,” said Acting Inspector General Joanne M. Chiedi. “We are proposing strong safeguards to protect patients from fraud and abuse by bad actors who might seek to misuse the new flexibilities.”

Below are examples involving coordinated care, value-based care, data sharing, and patient engagement activities that, depending on the facts, could currently be difficult to fit under existing protections and could potentially be protected by the Stark Law, Anti-Kickback Statute, or Civil Monetary Penalties Law proposals if all applicable conditions are met:

- In an effort to coordinate care and better manage the care of their shared patients, a specialty physician practice could share data analytics services with a primary care physician practice.
- Hospitals and physicians could work together in new ways to coordinate care for patients being discharged from the hospital. The hospital might provide the discharged patients’ physicians with care coordinators to ensure patients receive appropriate follow up care, data analytics systems to help physicians ensure that their patients are achieving better health outcomes, and remote monitoring technology to alert physicians or caregivers when a patient needs healthcare intervention to prevent unnecessary ER visits and readmissions.

- A physician practice could provide smart pillboxes to patients without charge to help them remember to take their medications on time. The practice could also provide a home health aide to teach the patient and the patient's caregiver how to use the pillbox. The pillbox could automatically alert the physician practice and caregiver when a patient misses a dose so they could follow up promptly with the patient.
- A local hospital could improve its cybersecurity and the cybersecurity of nearby providers that it works with frequently. To do so, it could donate, for free, cybersecurity software to each physician that refers patients to its hospital. The hospital and the physicians often share information about their patients, so it is important that there are no weak links that might compromise everyone else. The software would help ensure that hackers cannot attack the physician's computers. Improving each physician's cybersecurity would help prevent hackers from spreading the attack to other physicians and the hospital.
- To improve health outcomes for patients with end-stage kidney disease, a nephrologist, dialysis facility, or other provider could furnish the patients with technology that is capable of monitoring the patient's health and two-way, real-time interactive communication between the patient, facility, and physician. In addition, the facility could equip the physicians with data analytics software to help them monitor patients' health outcomes.

Read [OIG's proposed rule - PDF](#).*

Read [CMS's proposed rule - PDF](#).*

More on the changes to the [Stark Law](#).

More on the changes to the [Federal Anti-Kickback Statute - PDF](#).

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Last revised: October 9, 2019
