HEALTHCARE LEADERSHIP COUNCIL

Finalizing Stark and Anti-Kickback Reform: Essential Regulatory Reform to Improve Patient Care, Reduce Healthcare Costs

In October 2019, the Department of Health and Human Services (HHS) issued proposed regulations to modernize the Federal Physician Self-Referral (Stark) Law and the Anti-Kickback Statute. The intent of these proposed rules was to align federal fraud and abuse laws with an evolving, improved healthcare system focused on providing value rather than simply collecting payment for volume of care. These rules need to be finalized in order to remove obstacles standing in the way of achieving a patient-centered, value-driven, cost-efficient healthcare system in the United States.

The proposed rules maintain protections against fraud and abuse, while allowing for coordination and collaboration needed to improve the cost and quality of care.

- The Stark Law and Anti-Kickback Statute were designed for a fee-for-service system in which protections were necessary against those who would inappropriately influence medical decision-making and patient advice and encourage overutilization of services.

- Today, our healthcare system is increasingly reliant upon collaboration among physicians, hospitals, health plans, pharmaceutical and device manufacturers, and others who create an integrated care framework. Outdated rules and regulations impede efforts to wring unnecessary costs out of the system and improve health outcomes.

The benefits of this regulatory change will be significant for both patients and the healthcare system.

- Say, for example, a hospital contracts with a physician to construct and manage a team to coordinate care for a patient with multiple chronic conditions. Working in a more collaborative environment, that physician does an excellent job in enabling the patient to maintain good health status and avoid the costs associated with unnecessary hospital admissions and office visits. Under the current Stark Law, the hospital's compensation of that physician for outstanding work can be viewed as a violation.

- This is just one example detailing how an outdated regulatory system can act as a disincentive for healthcare providers to take innovative steps to coordinate care for patients with complex needs.

- Our healthcare system has the innovative capability to help patients live longer, healthier lives rather than simply treat their symptoms as they occur. Utilizing the full breadth of that system hinges on this regulatory modernization.

Stark and Anti-Kickback modernization will provide a valuable tool to constrain healthcare cost escalation.

- For example, a medical device manufacturer could provide a health system with a blood pressure monitoring device accompanied by health and nutrition support services to enhance patient care plans. The medical device manufacturer may wish to offer the health system a discounted rate for these goods and services if the patient doesn't reach agreed-upon health

outcomes. Under current law, this cost-saving agreement, tying payment to value, could be seen as a violation of the Anti-Kickback Statute.

- Plans, providers, and manufacturers are seeking to develop innovative ways to align dollars spent with healthcare value gained. Failure to align the fraud-and-abuse regulatory system with these changes will result in dollars spent inefficiently and avoidable increases in healthcare costs, which ultimately harm patients.

- Employers have long been calling for these types of changes to increase their competitiveness through reduced healthcare expenses and improve care coordination and health outcomes for their employees.

We can, and must, protect against the bad actors without obstructing essential, beneficial healthcare progress.

- Stark and Anti-Kickback modernization is not intended to weaken fraud and abuse protections. Rather, it provides vital safe harbors against unfair and counterproductive penalties for those seeking to bring greater value to the system through improved patient care delivered cost-effectively.

Patients and employers, and the healthcare system they depend on, need the current laws to be modernized in order to achieve a healthier and financially sustainable future.