Claire Turcotte
Partner

Cincinnati
513.870.6573
cturcotte@bricker.com

HHS regulatory sprint to coordinated care: Will meaningful changes make it across the finish line?

January 31, 2019

As part of the U.S. Department of Health and Human Services (HHS) initiative known as the "Regulatory Sprint to Coordinated Care" in 2018, HHS asked industry stakeholders for information regarding how it can improve both the federal Stark Law and the federal Anti-Kickback Statute (AKS) to reduce the regulatory burden of these laws and stop them from stifling innovation.

Specifically, on June 25, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a Request for Information (RFI) seeking public comments on how to remove Stark Law obstacles to the shift from fee-for-service to value-based payment models and coordinated care. CMS Administrator Seema Verma explained, "[w]e are looking for information and bold ideas on how to change the existing regulations to reduce provider burden and put patients in the driver's seat."

CMS asked for comments in three general areas:

- New Stark exceptions or changes to existing exceptions to facilitate alternative payment models (APMs) and similar integrated and coordinated care and risk-sharing models

- The applicability and utility of current exceptions for APMs and other novel models
- Additions or changes to key Stark Law definitions, such as the definitions of "commercial reasonableness," "fair market value" and "taking into account the volume or value of referrals" and terminology, such as "clinical integration," gainsharing" and "risk-sharing."

Likewise, on August 27, 2018, the HHS Office of Inspector General (OIG) issued a similar RFI seeking comments on the same types of issues, including possible changes to the AKS and the beneficiary inducement civil monetary penalties law, and:

- Details about new types of arrangements the industry is pursuing to promote care coordination, value-based payment, APMs, innovative technology and other novel financial arrangements
- Definitions of key terms, such as "value," "clinical integration," "risk-sharing" and others
- Types of beneficiary engagement incentives and cost-sharing initiatives used by providers, suppliers and others and how they may improve quality of care, care coordination and patient engagement
- Current fraud and abuse waivers available for certain APMs and whether they are burdensome or helpful
- The intersection of the Stark Law and the AKS and when these laws should have parallel exceptions or safe harbors and when they should not

CMS and OIG are currently reviewing comments and are expected to issue proposed rules in 2019 that could relax or create new exceptions and safe harbors, thereby removing obstacles to novel arrangements and facilitating the evolution towards value-based payment. For example, CMS may propose new Stark exceptions to protect accountable care organizations, bundled payments, shared-risk models and other novel arrangements. The outcome of this process could be a sweeping change to certain fundamental aspects of the fraud and abuse laws, giving a significant boost to payment and other innovation.