HHS Finalizes Changes to the Stark Law and Anti-Kickback Statute

By William P. Keefer
Phillips Lytle LLP

On December 2, 2020, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued *Revisions to the Safe Harbors Under the Anti-Kickback Statute (AKS) and Civil Monetary Penalty Rules Regarding Beneficiary Inducements*. The Centers for Medicare & Medicaid Services (CMS) also published the final rule *Modernizing and Clarifying the Physician Self-Referral Regulations* (commonly referred to as the "Stark Law").


William P. Keefer
Partner

The changes to the AKS and the Stark Law regulations come as part of the broader HHS "Regulatory Sprint to Coordinated Care," which was intended to remove potential regulatory barriers to care coordination and value-based care created by four health care laws and the associated regulations: (1) Stark Law; (2) AKS; (3) Health Insurance Portability and Accountability Act of 1996 (HIPAA); and (4) rules under 42 CFR Part 2 related to substance use disorder treatment.

The AKS is administered under the authority of OIG and imposes criminal penalties against those who knowingly and willfully offer, pay, solicit or receive remuneration to induce or reward the referral of business reimbursable under federal health care programs, such as Medicare or Medicaid. To ensure compliance with the AKS, health care providers may seek to voluntarily meet any number of "safe harbors."

The Stark Law is administered by CMS and prohibits physicians from making referrals of certain designated health care services to an entity with which the physician has a financial relationship, unless the transaction satisfies an exception to the Stark Law.

Many of the HHS changes add clarity, such as the newly codified definitions of terms like "commercially reasonable" and "fair market value." The new rules, however, also include more groundbreaking changes, such as the introduction of a value-focused regulatory scheme. Practitioners seeking safe harbors under the AKS, or exceptions under the Stark Law, now have the option to achieve compliance by advancing "value-based purposes," such as reducing costs to payors without reducing the quality of care for a target patient population.

AKS and Stark Law regulations now contemplate safe harbors and exceptions, respectively, where health care providers and suppliers collaborate utilizing "value-based entities" (VBEs) to take on financial risk, on a prospective basis, for the cost of items and services covered by a payor. In allocating financial risk to VBEs, HHS intends to incentivize and reward the efficient delivery of health care services, while allowing more flexibility for health care providers to develop innovative arrangements.

While one purpose of the new rules is to remove potential regulatory barriers to care coordination, the introduction of a new value-based vocabulary may have a chilling effect of its own, as the industry awaits further insight on permissible arrangements that may come in the form of OIG advisory opinions and U.S. Department of Justice False Claims Act enforcement. In any case, the new rules likely signal significant changes to the health care landscape going forward.

We note, however, that according to the U.S. Government Accountability Office, the revised regulations did not meet a 60-day delay requirement imposed by the Congressional Review Act intended to give Congress an opportunity to challenge agency rules. At this time, it is unclear whether the Biden administration will intervene to rescind, revise or reissue the rules.

William P. Keefer is a partner at Phillips Lytle LLP and leader of the firm's Health Care Law Practice Team. He counsels hospitals, physician groups, payors and other health care clients on a broad array of issues, including fraud and abuse, corporate compliance, transactional arrangements, payer audits, agency actions, and federal and state court litigation. He can be reached at wkeefer@phillipslytle.com or (716) 847-5488.