

CMS Issues Waivers to “Stark” Prohibitions and OIG Exempts Sanctions Under the Anti-Kickback Statute (AKS) in Response to the COVID-19 Pandemic

Stark and the AKS

The Physician Self-Referral Law, commonly referred to as “Stark,” prohibits physicians from referring Medicare and/or Medicaid patients to receive “designated health services” (DHS), including clinical laboratory services; physical, occupational, and/or speech-language therapy; radiology and/or other imaging services; durable medical equipment and supplies; prosthetics and/or orthotics; home health services; outpatient prescription drugs; and inpatient and outpatient services; from entities with which the physician or an immediate family member of the physician has a financial relationship, unless an exception applies (see 42 USC § 1395nn et seq.; see also 42 CFR § 411.350-389). The regulations that accompany the statute outline specific exemptions to the statutory prohibition for rental of certain office space, bona fide employment relationships and personal service arrangements (PSAs), but to qualify for those exemptions, the leases, employment contracts and PSAs have very specific requirements (see 42 CFR § 411.357); and the failure to comply with same risks significant civil monetary fines and exclusions from participation in federal health care programs, which can have severe adverse economic consequences on providers and health systems.

The AKS is similar in design to Stark but is a bit broader and is a criminal law, making the consequences more significant (see 42 USC § 1320a-7b(b)). The AKS prohibits “remuneration” to induce or reward patient referrals or generation of business involving any item or service payable by the federal government for medications, supplies or health care services for Medicare and/or Medicaid patients and the definition of “remuneration” is very broad. Specifically, remuneration is defined to include anything of value, including, but not limited to, cash, free rent, free marketing, monetary gifts and excessive compensation (see 42 USC § 1320a-7b(b)). Like with Stark, the AKS has exemptions, referred to as “safe harbors,” but typically the applicability of those is dependent on complying with very rigid terms.

Typically, ensuring compliance with Stark and the AKS and meeting the rigorous terms of the exemptions is a magnanimous task for health care providers, hospitals, and health systems. In particular, to meet the exemptions, written agreements need to be prepared in advance, and cannot be done “on the fly.” Additionally, under Stark, health care systems and hospitals that employ physicians also need to ensure the compensation of those physicians are paid is within “fair market value” (FMV). According to the regulations that accompany Stark, the purpose of the FMV requirement is to avoid overpaying physicians or compensating them based on the volume and value to their referrals, but that stringent requirement can certainly be an impediment in an emergency situation like the current health pandemic where a physician’s services are essential and may warrant a unique compensation arrangement not usually permitted by law.

Waivers to Stark in Response to COVID-19 Pandemic

On March 13, 2020, President Trump declared a national emergency under the Stafford Act, which allowed the U.S. Department of Health and Human Services (HHS) to take action under Section 1135 of the Social Security Act, and waive obligations that would otherwise be required under Medicare, Medicaid and the Children’s Health Insurance Program (CHIP). These are referred to as “blanket waivers.” Significant to this discussion, the “blanket” waivers exempt