

OIG Releases Policy Statement on AKS Enforcement Discretion During COVID-19 Pandemic

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Practice Area: Health Law

The Office of the Inspector General (“OIG”) has released a policy statement relating to its enforcement discretion under the Anti-Kickback Statute (“AKS”) during the COVID-19 pandemic. Essentially, the policy statement provides that the OIG will exercise its enforcement discretion not to impose administrative sanctions under AKS for certain limited arrangements already covered by the physician self-referral law (“Stark”) blanket waivers. Please see von Briesen COVID-19 Task Force *Updates* from March 30 and March 31, 2020, for further background on the Stark waivers. This *Legal Update* summarizes the policy statement and identifies issues providers should consider when assessing whether they may rely on that statement.

Limited Scope of Activities Covered by Policy. As noted in the OIG policy statement, some financial relationships that implicate Stark may also implicate and potentially violate the AKS. OIG will not impose administrative sanctions under the AKS for remuneration that relates to referrals for services furnished to federal health care program beneficiaries pursuant to arrangements that would be eligible for, and meet all of the requirements of, one of the Stark blanket waivers. The OIG policy does not cover remuneration that falls outside of those overlapping areas subject to possible sanctions under both AKS and Stark, however. So for example if an arrangement does not involve a financial relationship with a physician or immediate family member (and therefore not subject to Stark), the conduct could implicate the AKS but would not be covered by the policy statement. Also, the policy applies on a prospective basis to conduct on or after April 3, 2020 (unlike the Stark blanket waivers which were retroactive to March 1, 2020), but still expires at the same time as the blanket waivers. Finally, providers should keep in mind the discretionary waiver of enforcement authority only applies to financial relationships and referrals that are related to the national COVID-19 emergency and the remuneration and referrals must be related solely to COVID-19 purposes, much like the Stark blanket waivers—this is not a complete waiver of AKS enforcement authority.

Limited Scope of AKS vs. Stark. The AKS is still intent-based: at least one purpose of an arrangement must be to induce or reward referrals of federal program business in order for liability to attach. As a result, even if an arrangement potentially implicates the AKS but does not qualify under the OIG’s policy statement – for example because the arrangement is not a financial relationship covered under Stark, or because the remuneration is unrelated to COVID-19 purposes – providers still may not be subject to enforcement so long as the providers lack the requisite intent. The OIG’s exercise of enforcement discretion, while important, is therefore not quite as critical from an AKS perspective as the blanket waivers are under Stark’s strict liability regime.

Civil Monetary Penalty Laws. OIG's discretionary waiver of enforcement extends to potential civil monetary penalties under § 1128A(a)(7) of the Social Security Act "as those sections relate to the commission of acts described in the Federal anti-kickback statute." This waiver is limited specifically to those civil monetary penalties described at 42 U.S.C. § 1320a-7a(a)(7) for violations of the AKS, but does not extend to other civil monetary provisions under § 1128A(a)(7) of the Act such as those under sub (b) for payments to induce a reduction or limitation of services (so-called "gainsharing" arrangements). The provider community continues to look to OIG for guidance under those provisions insofar as these arrangements may offer additional tools for addressing the current pandemic.

Potential for Change. When the HHS Secretary announced the blanket waivers under Stark, the Secretary reserved the right to modify those waivers but expressly stated that any modification restricting the scope would be prospective only. The OIG statement also reserves the right to modify its policy but does not clearly state that any narrowing of the policy would be prospective only; prospective application might reasonably be assumed but it is not guaranteed.

Additional Guidance. In conjunction with the policy statement, the OIG released an FAQ relating to its enforcement discretion. The FAQ at this time only deals with arrangements whereby free or reduced rate services are furnished for nursing homes, but may be supplemented later with additional guidance.

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