

Insights

HHS OIG Adds New Authorities to the Anti-Kickback Statute and Civil Monetary Penalties Law

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The Health and Human Services Office of Inspector General (“OIG”) recently finalized new regulations (“Regulations”) impacting the anti-kickback statute (“AKS”) safe harbors and civil monetary penalties law (“CMPL”). Specifically, the Regulations expanded the exceptions and safe harbors under the AKS and CMPL as those apply to entities providing health care services to Medicare or Medicaid beneficiaries. The Regulations took effect on January 6, 2017.

In general, the AKS and the CMPL prohibit certain health care providers from offering “remuneration” in exchange for referrals or to induce Medicare or Medicaid beneficiaries to receive services covered under those programs. However, the OIG created several regulatory exceptions and safe harbors that protect conduct which may otherwise violate the AKS or the CMPL. The Regulations expand the list of safe harbors and exceptions by carving out certain conduct or activities from the term “remuneration,” though such changes do not apply to all health care providers.

In particular, the Regulations clarify when pharmacy providers and state or municipally owned emergency ambulance providers may waive a beneficiary's cost sharing obligations or when such ambulance providers may offer free or discounted local transportation services that meet specified criteria without violating the AKS. The Regulations also add new language protecting the provision of remuneration between Medicare Advantage organizations and Federally Qualified Health Centers and discounts by manufacturers of drugs furnished to beneficiaries under the Medicare Coverage Gap Program.

The changes to the CMPL primarily concern the relationship between the health care provider and a Medicare or Medicaid beneficiary. In broad terms, the CMPL prohibits a provider from offering remuneration to the beneficiary in order to induce that person's patronage. Under the Regulations, the term “remuneration” includes waiving or reducing a beneficiary's coinsurance or deductibles with certain limitations. Additionally, providers may offer “items or services” that either improve a beneficiary's access to Medicare or Medicaid services or offer items or services for free or less than fair market value so long as those arrangements comply with the Regulations.

The AKS and the CMPL are complex laws and application is generally fact specific. Please contact Brandon W. Shirley at bshirley@kdlegal.com if you have questions about the Regulations and potential impact on your business operations.