

## **Anti-Kickback Safe Harbor for Patient Engagement and Support**

Patient engagement, driven by IT tools, is as universal in today's environment as social media (in fact, Twitter, Instagram and YouTube have been used by the Mayo Clinic, the Cleveland Clinic and Johns Hopkins as a means to facilitate patient engagement). In short, the premise of patient engagement is that if patients are more involved in managing their own health, the behavior of these patients will more closely align with guidance prescribed to them by healthcare providers (such as adhering to prescription drug regimens, or dietary guidance), ultimately resulting in better clinical outcomes and diminished medical spending. Thus, the concept of patient engagement falls squarely into the healthcare system's shift to value-based care, as reflected by beneficiary engagement as a goal of MIPS and MACRA.

The OIG's newly-issued anti-kickback statute patient engagement and support safe harbor (the "Patient Engagement Safe Harbor") is consistent with the Medicare program's value-based care path.

- The Patient Engagement Safe Harbor only is available in the context of a "value-based arrangement," in which multiple "value-based enterprises" (VBEs) undertake activities with a "value-based purpose" for a "target patient population."
- Generally, the arrangement must entail the coordination or management of care for the applicable target population, so as to improve the quality of care and reduce costs (without impairing care quality).
- More specifically, prohibited remuneration under the anti-kickback statute will not include patient engagement tools or support provided by health system participants (such as clinicians, other providers and suppliers) to target population patients (government program beneficiaries), with certain limitations.
- The tools or support:
  - Must be in-kind, rather than in cash, and not exceed an annual value of \$500,
  - Are required to have a direct connection to the coordination and management of care of the target patient population,
  - Must promote satisfaction of pre-determined value-based goals, such as adherence to the patient's treatment or follow-up care plan or drug regimen, or disease prevention or management.

- The OIG specifically excluded certain health industry participants from qualifying as a VBE and thus taking advantage of protection under the Patient Engagement Safe Harbor, including pharmaceutical manufacturers and distributors, PBMs, compounding pharmacies, medical device manufacturers (with some exceptions), laboratories, and durable medical equipment suppliers.