KEY CHANGES TO THE ANTI-KICKBACK STATUTE AND CIVIL MONETARY PENALTY RULES

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On January 19, 2021, the final rule updating the safe harbors under the federal Anti-Kickback Statute ("AKS") and adding a new exception to the Beneficiary Inducements Civil Monetary Penalties ("CMP") takes effect. The Office of the Inspector General ("OIG") issued its final rule in conjunction with the Centers for Medicare and Medicaid Services ("CMS") final rule, modernizing the exceptions under the Medicare physician self-referral law (Stark Law), which we discuss in a corresponding alert here. The interwoven regulations are part of the "Regulatory Sprint to Coordinated Care" to remove potential regulatory barriers to care coordination and value-based care.

For years, stakeholders raised concerns that the existing regulatory structure had a chilling effect on innovation and the development of value-based care. The goal of the final rule is to protect certain value-based arrangements that would improve quality, outcomes and efficiencies. In the Preamble, the OIG suggests that the increased flexibilities may assist stakeholders in responding to and recovering from the COVID-19 public health emergency, as well as facilitate the development of sustainable value-based care delivery models for the future.

Here are some of the key changes:

1. New Value-Based Safe Harbors. The AKS final rule creates three new safe harbors for remuneration between or among participants in a value-based arrangement that fosters better coordinated and managed patient care. The value-based safe harbors apply to:

- **Care Coordination Arrangements** (¶ 1001.952(ee)) to improve quality, health outcomes and efficiency without requiring the parties to assume risk;
- **Value-Based Arrangements with Substantial Downside Financial Risk** (¶ 1001.952(ff)); and
- **Value-Based Arrangements with Full Financial Risk** (¶ 1001.952(gg)).

Attorneys

Christine Bonaguide
David Bradley
Jane Bello Burke
Roopa Chakkappan
Reetuparna Dutta
Joshua Feinstein
Peter Godfrey
Charles H. Kaplan
Michelle Merola
Matthew Scherer
Gary Schober
David Stark

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The value-based safe harbors vary based on the types of remuneration protected, the types of entities that can rely on them, the level of financial risk the parties assume, and the types of safeguards included as conditions. The definitions applicable to the value-based safe harbors under the AKS largely align with the definitions applicable to the value-based exceptions under the Stark Law.

To illustrate, assuming satisfaction of the applicable requirements, the value-based safe harbors could apply to a hospital's provision of care managers to a physician group to assist with patients' post-discharge transition services, such as medications or home-based care, or to a medical technology company's provision of digital health technology to a physician group to alert the group's physicians when the patient needs health care interventions to avoid unnecessary readmission.

2. Other New Safe Harbors. The final rule also creates additional safe harbors as follows:

- **Patient Engagement and Support Safe Harbor** (§ 1001.952(hh))
  - This allows for a participant in a value-based enterprise to furnish non-monetary tools and supports to a patient in a target patient population to coordinate care, and improve quality and health outcomes.
  - Examples might include a physician practice providing low-income patients with transit cards or taxi vouchers to encourage mammogram screenings.
- **CMS-Sponsored Models Safe Harbor** (§ 1001.952(ii))
  - This is intended to reduce the need for the OIG to issue separate fraud and abuse waivers for new CMS-sponsored healthcare delivery models.
  - Examples might include instances where a Medicare Shared Savings program provides beneficiaries with glucose meters for diabetes patients to monitor blood sugar levels.
- **Cybersecurity Technology and Services Safe Harbor** (§ 1001.952(jj))
  - This protects remuneration in the form of non-monetary donations of certain cybersecurity technology and services to facilitate improved cybersecurity in healthcare and to guard against security threats.
  - Examples might include a hospital's donation of cybersecurity encryption software to a local physician practice to ensure the secure transfer of protected health information.
- **Medicare Shared Savings ACO Beneficiary Incentives** (§ 1001.952(kk))
  - This codifies the statutory exception of remuneration related to incentive payments to assigned Medicare beneficiaries under an Accountable Care Organization's Beneficiary Incentive Program.
  - Examples might include a $20 debit card to encourage beneficiaries to obtain medically necessary primary care services.

3. Modified Safe Harbors. Additionally, the final rule modifies the following existing safe harbors:

- **Personal Services and Management Contracts and Outcome-Based Payments** (§ 1001.952(d))
  - This increases flexibility for part-time or sporadic arrangements by removing the requirement that the agreement set in advance the exact schedule and length of services and the charge for such intervals.

- An example might involve a home care agency's engagement of a part-time care coordinator as an independent contractor on an intermittent basis to assist discharged nursing facility patients with in-home care.
- This also expands the safe harbor to include "outcomes-based payment" arrangements that either reward improving patient health outcomes by achieving outcome measures across care settings, or reducing payor costs while maintaining or improving quality of care for patients.
- An example might involve an outcome-based payment arrangement involving a hospital and physician group sharing financial risk or gain realized across care settings for a patient's inpatient stay and the 60 day post-discharge period.

- **Warranties** (§ 1001.952(g))
  - This revises the definition of "warranty" to include an affirmation of fact or written promise relating to bundled items and related services.
  - An example might involve a drug manufacturer's offer to a hospital of a warranty program covering patient self-injected drug products and education services reimbursable under a bundled prospective payment model.
- **Electronic Health Records Safe Harbor** (§ 1001.952(y))
  - This modifies the existing safe harbor for electronic health record (EHR) items and services to update and remove provisions regarding interoperability, remove the sunset provision and prohibition on donation of equivalent technology, and clarify protections for cybersecurity technology and services included in an EHR arrangement.
  - An example might involve a health system's donation of certified EHR software to physicians in its provider network to enhance care coordination.
- **Local Transportation** (§ 1001.952(bb))
  - This expands mileage limits for rural areas (up to 75 miles), eliminates mileage limits for transportation to convey patients discharged from the hospital to their place of residence, and clarifies the availability of the safe harbor for transportation through rideshare arrangements.
  - An example might involve a hospital's offer of a free non-luxury shuttle to transport discharged patients to their residences irrespective of the distance.

4. Beneficiary Inducements CMP. Further, the final rule adds the following exception to the Beneficiary Inducements CMP:

- **Telehealth for In-Home Dialysis Patients** (§ 1002.110).
  - This codifies the statutory exception for "telehealth technologies" furnished to certain in-home dialysis patients. The term "telehealth technologies" means hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention, or ongoing care management.
  - An example might involve a renal dialysis center's provision of a device to an existing Medicare End-Stage Renal Dialysis patient to facilitate the use of telehealth services for in-home dialysis.

The final rule, which is available to view here, provides extensive commentary on the changes.

If you need assistance in analyzing or applying these changes in the context of current or prospective arrangements, please contact Jane Bello Burke (518.433.2404), Joshua Feinstein (716.848.1318) or Roopa Chakkappan (716.848.1258).

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