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Health Care Advisory

OIG Proposes to Add and Expand AKS Safe Harbors

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"OIG Proposes to Add and Expand AKS Safe Harbors" is Part II of a two-part series discussing the US Department of Health and Human Services' (DHHS) recent proposed rules revising the Stark Law and the Anti-Kickback Statute regulations as part of DHHS' Regulatory Sprint to Coordinated Care. Part I, "CMS Proposes Sweeping Revisions to the Stark Law" is available here. Part II relates to the Anti-Kickback proposed rule.

KEY POINTS

- On October 17, 2019, the OIG proposed rules to add safe harbor protections for coordinated care and associated value-based arrangements.
- The OIG proposed several new safe harbors: value-based enterprise, patient engagement and support, CMS-sponsored models, and cybersecurity technology; and modified certain existing safe harbors: EHR, personal services, warranties, and local transportation.
- The OIG also proposed to codify the statutory exception to the definition of "remuneration" for certain telehealth technologies offered to patients receiving in-home dialysis under the civil monetary penalty law.
- Comments on the proposed rules are due by December 31, 2019.

On October 17, 2019, the Office of Inspector General (OIG) proposed rules to add safe harbor protections under the Federal anti-kickback statute (AKS) for certain coordinated care and associated value-based arrangements between or among clinicians, providers, suppliers, and others. The proposed rule would add protections under the AKS and civil monetary penalty (CMP) law for certain patient engagement and support arrangements to improve quality of care, health outcomes, and efficiency of care delivery. The proposed rule also would add new safe harbors for donations of cybersecurity technology and certain beneficiary incentives under the Medicare Shared Savings Program (MSSP), as well as a new CMP exception for certain telehealth technologies offered to patients receiving in-home dialysis. It also would amend the existing safe harbors for electronic health records (EHR) arrangements, warranties, local transportation, and personal services and management contracts.

In the preamble to the proposed rule, the OIG acknowledged that the broad reach of the AKS (42 U.S.C. § 1320a-7b(b)) and the CMP law provision prohibiting inducements to beneficiaries (42 U.S.C. § 1320a-7a(a)(5)) might inhibit beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care. The OIG also recognized that, because the consequences of potential noncompliance with these statutes could be dire, providers and suppliers may be discouraged from entering into innovative arrangements that would improve quality and health outcomes, produce system efficiencies, and lower costs.

The OIG followed several guiding principles in developing the proposed regulations, including designing proposed safe harbors that allow for beneficial innovations in health care delivery; avoiding safe harbors and exceptions that drive such innovation to limited channels that may not reflect up-to-date understandings in medicine, science, and technology; and designing proposed safe harbors useful for a range of individuals and entities engaged in the coordination and management of patient care.

The OIG cautioned that the proposed safe harbors remain subject to change through the rulemaking process, and that any final safe harbors would provide only prospective protection.

New proposed safe harbors

The OIG proposed several new AKS safe harbors:

- **Value-based enterprise (VBE) safe harbors** would protect certain remuneration exchanged between or among participants in a value-based arrangement that fosters better coordinated and managed patient care:
  - ***Care coordination arrangements to improve quality, health outcomes, and efficiency*** (§ 1001.952(ee)) applies to certain in-kind remuneration, including services and infrastructure, exchanged between qualifying VBE participants in value based arrangements;
  - ***Value-based arrangements with substantial downside financial risk*** (§ 1001.952(ff)) protects certain in-kind and monetary remuneration and offers greater flexibility in recognition of a VBE's assumption of substantial downside financial risk from a payor; and
  - ***Value-based arrangements with full financial risk*** (§ 1001.952(gg)) covers certain in-kind and monetary remuneration and offers even more flexible conditions, because VBEs that assume full downside financial risk from a payor present fewer traditional fee-for-service fraud and abuse risks.
- **Arrangements for patient engagement and support to improve quality, health outcomes and efficiency** (§ 1001.952(hh)), furnished by VBE participants to specified patients, is intended to remove barriers presented by the AKS and the beneficiary inducement CMP to providers offering patients beneficial tools and supports to improve quality, health outcomes and efficiency, by promoting patient engagement with their care and adherence to care protocols.
- **CMS-sponsored model arrangements and CMS-sponsored model patient incentives** (§ 1001.952(ii)) would permit remuneration among parties to arrangements (e.g., distribution of capitated payments, shared savings or losses) under CMS sponsored models and initiatives and to permit remuneration in the form of incentives and supports provided by CMS model participants under a CMS-sponsored model to patients covered by such model. This safe harbor would standardize and simplify AKS compliance for CMS-sponsored model participants and reduce the need for OIG to issue distinct fraud and abuse waivers for new CMS-sponsored models.
- **Cybersecurity technology and related services** (§ 1001.952(jj)) would protect donations of certain cybersecurity technology and related services to improve cybersecurity posture of the health care industry by removing a real or perceived AKS barrier and to allow parties to address the growing threats of cyberattacks.

Modifications to existing safe harbors

The OIG also proposed to modify certain existing AKS safe harbors:

- **Electronic health records items and services** (§ 1001.952(y)) would add protections for certain cybersecurity technology included in an electronic health records arrangement, update provisions regarding interoperability, and remove the sunset date.

- **Personal services and management contracts** (§ 1001.952(d)) is a proposal to:
  - substitute the requirement that ***aggregate compensation*** over the arrangement's term be set in advance with a requirement that the ***compensation methodology*** be set in advance, thus adopting a similar approach to the comparable Stark Law exception;
  - eliminate the requirement that a part-time arrangement must specify the schedule, length and exact charge for each interval of service; and
  - extend the safe harbors to certain outcomes-based payments tied to measurable improvements in the quality of patient care or to reductions in payor costs or the growth of payor expenditures (but not when payments relate solely to the principal's internal cost savings).
- **Warranties** (§ 1001.952(g)) expands the definition of "warranty," to cover bundled items and services under certain conditions (not just single items) and to exempt beneficiaries from the reporting requirements applicable to buyers. Notably, warranties cannot be conditioned on exclusivity or minimum purchase requirements.
- **Local transportation** (§ 1001.952(bb)) expands the distance that residents of rural areas may be transported from 50 miles to 75 miles and to remove any mileage limit on transportation of a patient upon discharge from a health care facility to the patient's residence. In addition, the preamble clarifies that the safe harbor may apply to transportation provided through ride-sharing services.

ACO Beneficiary Incentive Program

The proposed rule codifies the statutory exception to the definition of "remuneration" (42 U.S.C. § 1320a-7b(b)(3)(K)) to carve out incentives paid to promote beneficiary use of certain primary care services under an ACO Beneficiary Incentive Program for the MSSP (§ 1001.952(kk)). While the regulatory language is nearly identical to the statutory language, it clarifies that ACOs may pay incentives only to assigned beneficiaries.

Civil Monetary Penalty Law

The OIG proposes to amend the definition of "remuneration" in the CMP rules (§ 1003.110) by incorporating a new statutory exception to the prohibition on beneficiary inducement for telehealth technologies furnished to certain in-home dialysis patients. The OIG also notes that the proposed new safe harbor for patient engagement and support arrangements (§ 1001.952(hh)) and the proposed modifications to the local transportation safe harbor (§ 1001.952(bb)) would by operation of law serve as exceptions to the definition of "remuneration" under the beneficiary inducement CMP.

Conclusion

Providers should carefully consider how the new regulations might impact their existing or planned arrangements and whether to submit comments to CMS.

CONTACTS

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