



Innovate and Pay for Value: Goals of New Anti-Kickback and Civil Monetary Penalty Rules

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Peppered with references to ride sharing, interoperability, cybersecurity, and electronic health records, the Office of Inspector General's (OIG) proposed rules to the Anti-Kickback Statute and Civil Monetary Penalty Rules read like they were drafted by a Silicon Valley health app developer. The 386-page notice of proposed rulemaking seeks comment on revisions of the safe harbors to the Federal Anti-Kickback Statute ([42 U.S.C. § 1320a-7b\(b\)](#); "AKS") and the Federal Civil Monetary Penalty ([42 U.S.C. § 1320a-7a\(a\)\(5\)](#); "CMP") rules regarding beneficiary inducements. It also demonstrates a focus on permitting innovative arrangements and a shift to value-based care.^[1] Generally, the proposed rule seeks to add the following:

- new safe harbor protections to the AKS for certain coordinated care and associated value-based arrangements between or among clinicians, providers, suppliers, and others; and
- new protections under the AKS and CMP law that prohibit inducements offered to patients for certain patient engagement and that support arrangements to improve quality of care, health outcomes, and efficiency of care delivery.

This proposed rule is part of the Department of Health and Human Services' (HHS) "Regulatory Sprint to Coordinated Care," which aims to reduce regulatory barriers and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination.

HHS stated that it recognizes the broad reach of the AKS, and the CMP penalty for beneficiary inducements, as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care among providers and across care settings in both the federal healthcare

programs and commercial sector.

The proposals seek to promote flexible, industry-led innovation in the delivery of more efficient and better coordinated healthcare and support a more rapid transition from volume (e.g., FFS reimbursement for office visits, tests, or procedures) toward value (e.g., paying for patient or population outcomes).

What do the proposed changes include?

AKS Changes

The OIG proposes to amend 42 CFR 1001.952 by modifying certain existing safe harbors to the AKS and by adding safe harbors that would provide new protections or codify an existing statutory protection.

- **Value-Based Arrangements.** Three proposed new safe harbors for certain remuneration exchanged between or among eligible 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));
 - Value-Based Arrangements With Substantial Downside Financial Risk (§ 1001.952(ff)); and
 - Value-Based Arrangements With Full Financial Risk (§ 1001.952(gg)). These proposed safe harbors vary by the types of remuneration protected, level of financial risk assumed by the parties, and types of safeguards included as safe harbor conditions.
- **Patient Engagement.** A proposed new safe harbor (§ 1001.952(hh)) for certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency.
- **CMS-Sponsored Models.** A proposed new safe harbor (§ 1001.952(ii)) for certain remuneration provided in connection with a CMS-sponsored model (as defined in the proposed rule), which should reduce the need for separate and distinct

fraud and abuse waivers for new CMS-sponsored models.

- **Cybersecurity Technology and Services.** A proposed new safe harbor (§ 1001.952(jj)) for donations of cybersecurity technology and services.
- **Electronic Health Records Items and Services.** Proposed modifications to the existing safe harbor for electronic health records items and services (§ 1001.952(y)) to add protections for certain related cybersecurity technology, to update provisions regarding interoperability, and to remove the sunset date.
- **Outcomes-Based Payments and Part-Time Arrangements.** Proposed modifications to the existing safe harbor for personal services and management contracts (§ 1001.952(d)) to add flexibility with respect to outcomes-based payments and part-time arrangements.
- **Warranties.** Proposed modifications to the existing safe harbor for warranties (§ 1001.952(g)) to revise the definition of “warranty” and provide protection for bundled warranties for one or more items and related services.
- **Local Transportation.** Proposed modifications to the existing safe harbor for local transportation (§ 1001.952(bb)) to expand and modify mileage limits for rural areas and for transportation for patients discharged from inpatient facilities.
- **Accountable Care Organization (ACO) Beneficiary Incentive Programs.** Codification of the statutory exception to the definition of “remuneration” related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (§ 1001.952(kk)).

CMP Changes

The OIG proposes to amend the definition of “remuneration” in the CMP rules at 42 CFR 1003.110 by interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for “telehealth technologies” furnished to certain in-home dialysis patients, pursuant to section 50302(c) of the Budget

Act of 2018.

Further, note that if finalized, 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 beneficiary inducements CMP prohibition's definition of "remuneration."

Conclusion

The OIG is soliciting public comments on these proposed changes for 75 days following the publication date of the Notice of Proposed Rulemaking in the Federal Register. For further information and to access the proposed rulemaking, please visit:

<https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp>.

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[1] A copy of the proposed rule is available at <https://go.usa.gov/xVMSs> and a "fact sheet" discussing the proposed rule is available at <https://go.usa.gov/xVMSH>.

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