

# Health Information Compliance Alert

## Fraud & Abuse: Don't Miss IT-Related Updates to AKS

### See new safe harbors to promote value-based care.

The feds are on a mission to reduce administrative burdens, cut costs, and increase cooperation between providers and suppliers. Now, they've turned the spotlight on fraud and abuse regulations, offering some health IT updates to encourage care coordination.

**Context:** On Oct. 17, the **HHS Office of Inspector General** (OIG) published proposed rulemaking in the Federal Register that aligns with the HHS Regulatory Sprint to Coordinated Care, impacting Civil Monetary Penalties (CMPs) and the Anti-Kickback Statute (AKS). The proposed updates, titled "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," revamp old safe harbors and introduce a few new ones to improve value-based arrangements.

**Remember:** AKS "applies to any financial arrangement that impacts federal health care program beneficiaries, e.g., TriCare and other programs in addition to Medicare and Medicaid," explains attorney **Linda Baumann**, partner with **Arent Fox** in Washington, D.C.

"AKS is violated when a payment is made based on the 'volume or value of referrals' with the term 'referral' being interpreted such that a sale's rep delivering a prescription to a pharmacy could be considered a referral," adds attorney **John E. Morrone**, partner with **Frier Levitt LLC** in New York City.

### Review OIG's Reasoning

Currently, AKS regulations and CMPs inhibit "beneficial arrangements" and thwart "value-based care" in "both federal healthcare programs and the commercial sector," according to the OIG fact sheet on the proposed rule. Plus, several new safe harbors are on the table to improve patient engagement, interoperability, and quality care.

Read on to see how OIG plans to renovate AKS and CMPs:

- **Risk and reward:** The proposed rulemaking addresses "certain remuneration exchanged between or among eligible participants in a value-based arrangement" with three safe harbors, which vary based on the level of financial risk and care coordination, suggests the fact sheet.
- **Quality:** The feds recommend a safe harbor to bump up patient engagement and align with the quality objectives.
- **ACOs:** A CMS payment model safe harbor aims to revise compensation policies and cut down on the need for fraud and abuse waivers. There is also a proposal to improve the Accountable Care Organization Beneficiary Incentive programs through the Medicare Shared Savings Program.
- **Data security:** Cybersecurity gets a boost with a new proposed safe harbor to better protect organizations' and patients' personal and medical information.
- **EHRs:** Proposed modifications focus on better aligning current EHR safe harbors with technological advancements and updates.
- **Contracts:** The proposed rule introduces modifications to current safe harbors for personal services and management contracts for "flexibility with respect to outcomes-based payments and part-time arrangements," notes the fact sheet.
- **Warranties:** The proposal offers a safe harbor makeover for warranties that includes a revised definition and safeguards for bundled services.
- **Transportation:** Discharges and rural medicine are in the rule with new transportation safe harbors.
- **Telehealth:** In-home dialysis may get a CMP exception for telehealth services, the rule indicates.

**Industry input:** The **American Medical Association** (AMA) agrees with the OIG that the AKS needs a facelift to promote value-based care, improve coordination, and accommodate new technology. The AMA will work with the feds to "update and modernize the fraud and abuse laws and regulations to address changes in the health care delivery and payment systems," says **Patrice M. Harris, MD, MA**, AMA president, in a release.

The deadline to submit comments on the proposed rule is Dec. 31.

**Note:** Review the proposed rule at [www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the](http://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the).