

LETTERHEAD

DATE

Submitted electronically via www.regulations.gov

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Joanne Chieti, Acting Inspector General
Office of Inspector General
Department of Health
and Human Services
Attention: OIG-0936-AA10-P,
Room 5521, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

**Re: CMS-1720-P: Modernizing and Clarifying the Physician Self-Referral Regulations
and OIG-0936-AA10-P: Revisions to Safe Harbors Under the Anti-Kickback Statute**

Dear Administrator Verma and Inspector General Chieti:

On behalf of [INSERT name of organization], thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule modernizing and clarifying the physician self-referral regulations (CMS-1720-P) (the "Stark Proposed Rule"), and to the Department of Health and Human Services Office of the Inspector General's (HHS-OIG's) proposed rule revising safe harbors under the Anti-Kickback Statute (OIG-0936-AA10-P) (the "AKS Proposed Rule").

[INSERT narrative about your organization or facility, and the population you serve.]

[INSERT name of organization] supports the establishment of new safe harbors under the Anti-Kickback Statute and new Stark exceptions specific to value-based arrangements. We agree with HHS that these rules would provide greater certainty for healthcare providers participating in value-based arrangements and providing coordinated care for patients. Such changes are necessary as payers and providers alike seek to limit healthcare costs while maintaining high-quality care by shifting to a payment paradigm based on value rather than volume. [INSERT name of organization] believes that these proposals, if finalized, would strike an appropriate balance easing the compliance burden for healthcare providers and maintaining strong safeguards to protect the patients we serve.

[IF AVAILABLE, ADD EXAMPLE OF VALUE-BASED ARRANGEMENT THAT ORGANIZATION/AGENCY IS CONSIDERING OR MIGHT CONSIDER IF MORE DEFINITIVE SAFE HARBOR PROTECTION IS PROVIDED]

In finalizing both the Anti-Kickback and Stark Proposed Rules, [INSERT name of organization] encourages OIG and CMS to be cognizant both of the speed of technological progress in the healthcare industry and the inherently complex and difficult-to-foresee nature of compliance issues that may arise in developing innovative payment approaches to promote value-based care. To mitigate the risk that the safe harbors and exceptions established *today* do not inadvertently undercut future innovative payment models *tomorrow* by preemptively making them ineligible for protection, we believe this weighs in favor of promoting flexibility in providing protection for value-based arrangements and other efforts to drive coordinated care..

Likewise, to promote flexibility, we encourage CMS and OIG to harmonize its proposed exceptions and safe harbors for value-based arrangements and CMS-sponsored model arrangements to the extent feasible, to ensure that payment innovations that are viewed as worthy of protection under one statute are not chilled as a result of being left in regulatory limbo under the other. We similarly urge OIG to adopt a flexible approach when finalizing both the new proposed safe harbor for patient engagement and support tools and in making changes to the safe harbor for local transportation. We have found the ability to meet the patient *where* they are, with the tools and supports *they need*, is critical to fostering successful patient outcomes. Although the provision of low-cost or free tools and supports has the potential to raise concerns under applicable fraud and abuse laws, our experience also shows that these tools and supports are often the most-needed and offer the most cost-effective pathway toward care coordination. We urge the agencies to provide robust and broad protection for patient engagement and support tools going forward.

[INSERT name of organization] strongly supports the Anti-Kickback and Stark revisions proposed by OIG and CMS, and applauds both agencies for their proposals to remove unnecessary and burdensome regulations that stand in the way of innovative payment models to promote value-based care that improve outcomes for the patients we serve every day. In keeping with OIG's and CMS' promising proposals, we respectfully encourage both agencies to prioritize regulatory flexibility in finalizing these regulations to ensure that the fraud and abuse laws in the future continue to protect the public's money but do not stand as an obstacle to cost-effective and high-quality patient care.

Thank you for your consideration of our comments. If you have any questions, please contact [INSERT contact information]

Sincerely,

[SIGNATORY]
[POSITION]