

OIG SOLICITS COMMENTS TO PROPOSED MODIFICATIONS TO ANTI-KICKBACK REGULATIONS, INCLUDING ADDITION OF VALUE-BASED ARRANGEMENTS, PATIENT INVOLVEMENT, CYBERSECURITY AND CMS-SPONSORED MODELS

Hodgson Russ Healthcare Alert
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On October 9, 2019, the Office of Inspector General (OIG) of the Department of Health and Human Services released a proposed rule to add new safe harbors and revise existing safe harbors under the Anti-Kickback Statute and Civil Monetary Penalty rules. This rule is part of the Regulatory Sprint To Coordinated Care, an initiative by HHS which seeks to improve healthcare by examining federal regulations that impede efforts among providers to coordinate care.

The proposed rule creates three new safe harbors for remuneration received between participants in value-based arrangements that range from full risk bearing arrangements to arrangements with little or no risk that still include value. Value-based arrangements would protect certain in-kind and monetary remuneration to health care providers under already existing programs that are designed to improve quality, health care outcomes and control costs.

Additionally, the proposed rule creates three *new* safe harbors to encourage patient involvement, guard against cybersecurity threats and protect remunerations associated with alternative payment models.

- **Patient Engagement and Support safe harbor (42 CFR §1001.952 (gg))** The rule would allow for certain tools and supports furnished under patient engagement and support arrangements to improve quality, and health outcomes. Examples would include instances where a hospital provides an asthmatic child's caregiver with an oxygen purification system for home use to reduce the number of hospitalizations.
- **Cybersecurity Technology and Services (42 CFR §1001.952 (jj))** The rule would provide protections for donations of cybersecurity technology and services to guard against security threats from interconnected systems. Examples would include a hospital's donation of cybersecurity encryption software to a local

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physician practice that refers patients to the hospital.

- **CMS-Sponsored Models (42 CFR §1001.952 (ii))** The rule would allow certain remuneration provided in connection with a CMS-sponsored model, which should reduce the need for the OIG to issue separate fraud and abuse waivers for new CMS-sponsored models. Examples would include instances where a Medicare Shared Savings program provides beneficiaries with glucose meters for diabetes patients to monitor blood sugar levels.

Lastly, the proposed rule modifies *existing* safe harbors such as:

- **Electronic Health Records Items and Services (42 CFR §1001.952 (y))** The rule adds protections to update provisions regarding interoperability and removes the sunset date. For example, an ACO (Accountable Care Organization) donates certified EHR software to physicians in its provider network to enhance care coordination.
- **Personal Services and Management contracts (42 CFR §1001.952 (d))** The rule adds flexibility to allow outcome-based payments and certain part-time arrangements. For example, the amendment should make it easier for a home care agency to engage a part-time care coordinator as an independent contractor on an intermittent basis to assist discharged nursing facility patients with in-home care protocols.
- **Warranties (42 CFR §1001.952 (y))** The rule revises the definition of warranty from a single item to bundled items and related services. For example, the amendment should make it easier for a wound care product manufacturer to offer hospitals a warranty program covering wound care products and services reimbursable under a bundled prospective payment model.
- **Local Transportation (42 CFR §1001.952 (bb))** The rule would expand and modify mileage limits for rural areas and for transportation for patients discharged from inpatient facilities. For example, the amendment should make it easier for a hospital to offer a free non-luxury shuttle to transport discharged patients to their residences irrespective of the distance.
- **Accountable Care Organization (ACO) Beneficiary Incentive Programs** The rule provides a definition of remuneration related to the ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program. For example, the amendment should make it easier for an ACO to provide a \$20 debit card to Medicare beneficiaries as an inducement to attend mammography visits.
- **Civil Monetary Penalty Authorities and Telehealth for In-Home Dialysis** The rule amends the definition of remuneration in the CMP (Civil Monetary Penalty) rules to protect beneficiary inducements for “telehealth technologies” furnished to certain in-home dialysis patients. For example, this amendment should make it easier for a renal dialysis center to provide an existing End Stage Renal Dialysis patient with a smartphone to facilitate the use of “telehealth” services for in-home dialysis.

OIG is soliciting comments in many areas, including:

- whether gift cards should be provided as patient engagement tools and supports

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- whether the Electronic Health Record recipient contribution requirements should be eliminated for all recipients
- whether pharmaceutical manufacturers, durable medical equipment manufacturers, suppliers, and distributors and laboratories should be excluded from the outcomes-based payments safe harbor
- whether the transportation safe harbor should include non-medical purposes, such as transportation to food banks or social service facilities
- whether the CMP rules and telehealth exception should also be applicable to suppliers

The proposed rule can be accessed at <https://www.hhs.gov/sites/default/files/oig-nprm.pdf>. Comments must be submitted by December 31, 2019.

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