

OIG FINALIZES NEW AND REVISES EXISTING AKS SAFE HARBORS AND CREATES NEW CMP LAW EXCEPTION

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U.S. Health Care Alert

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On 2 December 2020, the Office of Inspector General (OIG) in the U.S. Department of Health & Human Services (HHS) issued a long-awaited final rule (the Final Rule or Rule).¹ The Final Rule adds multiple new safe harbors and revises several existing safe harbors under the federal Anti-Kickback Statute (AKS) as well as adding new protections under the Civil Monetary Penalties Law (CMP Law) that were first addressed in the October 2019 proposed rule.² The Final Rule is a key part of HHS's Regulatory Sprint to Coordinated Care, which aims to remove potential regulatory barriers to care coordination and value-based care created by applicable health care laws. HHS identified the broad reach of the AKS and the prohibition on beneficiary inducements in the CMP Law 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 the context of both Federal health care programs and the commercial sector. This client alert details (i) three new safe harbors under the AKS (note that additional value based care rules will be addressed in a forthcoming client alert and that the Stark Law changes are addressed in a recent client alert found [here](#)), (ii) four modifications to existing AKS safe harbors, and (iii) new protections under the CMP Law related to telehealth technologies and end-stage renal disease (ESRD) patients.

The changes in the Final Rule related to AKS safe harbors and the CMP Law exception are aimed at removing existing barriers to more efficient and effective care.

More specifically, the following changes to the AKS safe harbors and CMP Law are of particular note. The Final Rule does the following:

Cybersecurity Technology and Services

Adds a new AKS safe harbor related to donations of cybersecurity technology and services in order to facilitate improved cybersecurity in health care delivery. (1001.952 (jj))

CMS-Sponsored Models

Includes a new AKS safe harbor related to CMS-sponsored models, as defined in the Rule. This is meant to eliminate fraud and abuse waivers requested in connection with these Models. (1001.952(ii))

Accountable Care Organization (ACO) Beneficiary Incentive Program

Codifies the statutory exception to the definition of "remuneration" under the AKS related to the ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program. (1001.952(kk))

Electronic Health Records Items and Services

Modifies the existing AKS safe harbor to allow for a number of provisions, such as clarifying protections for cybersecurity, removing the sunset date, and addressing interoperability issues. (1001.952 (y))

Personal Services and Management Contracts and Outcome-Based Payment Arrangements

Modifies the existing AKS safe harbor to increase flexibilities for part-time and sporadic arrangements and to protect certain outcome-based payment arrangements. (1001.952(d))

Local Transportation

Modifies the existing AKS safe harbor for transportation by expanding mileage limits and clarifying that rideshare arrangements are protected. (1001.952 (bb))

Warranties

Modifies the existing AKS safe harbor for warranties to extend the protection for services as well as items, provided those services are bundled with or related to the items being provided. (1001.952 (g))

CMS Change for Telehealth for In-House Dialysis

Amends the definition of remuneration to codify a new exception to address “telehealth technologies” furnished to certain in-house dialysis patients. (42 CFR 1003.110)

Further changes are outlined in our [accompanying White Paper](#).

As highlighted above, this alert focuses on the non-value-based care changes and additions to the Final Rule, detailing three new safe harbors and four changes to existing safe harbors under the AKS, as well as highlighting a new codification under the CMP Law. These changes and clarifications will undoubtedly impact many aspects of health care providers' daily operations and strategic planning.

K&L Gates' health law team regularly advises hospitals, health systems, academic medical centers, and providers of all types on all aspects of AKS and CMP compliance, including interpretation and application of safe harbors, regulatory analysis of existing and proposed arrangements, and risk management.

FOOTNOTES

¹ Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (Dec. 2, 2020).

² Revisions to the Safe Harbor Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55,694 (proposed Oct. 17, 2019).

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