



HHS Office of Inspector General Fact Sheet

**Final Rule: Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements
November 2020**

Background

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) is publishing a final rule (Final Rule), “Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements.” This Final Rule is part of HHS’s Regulatory Sprint to Coordinated Care (Regulatory Sprint), which aims to reduce regulatory barriers to care coordination and accelerate the transformation of the health care system into one that better pays for value and promotes care coordination.

HHS has identified the broad reach of the Federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and the civil monetary penalty (CMP) law provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP), 42 U.S.C. § 1320a-7a(a)(5), as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care across care settings in both the Federal health care programs and commercial sector.

The Federal anti-kickback statute provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward, among other things, the referral of business reimbursable under any of the Federal health care programs, including Medicare and Medicaid. Health care providers and others may voluntarily seek to comply with statutory and regulatory safe harbors so that they have the assurance that their business practices will not be subject to sanctions under the anti-kickback statute. To receive safe harbor protection, an arrangement must squarely meet each requirement of an applicable safe harbor. However, failure to fit in a safe harbor does not mean that an arrangement violates the Federal anti-kickback statute. Arrangements that do not fit in a safe harbor are analyzed on a case-by-case basis, including whether the parties had the requisite intent. Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the health care industry.

The Beneficiary Inducements CMP provides for the imposition of CMPs against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program.

OIG promulgated a Notice of Proposed Rulemaking (NPRM) on October 17, 2019.¹ OIG coordinated with the Centers for Medicare & Medicaid Services (CMS), which also issued an NPRM in October 2019, and is concurrently issuing a final rule in connection with the Regulatory Sprint. In response to OIG’s NPRM, we received 337 public comments, which

¹ See 84 Fed. Reg. 55,694 (Oct. 17, 2019), available at <https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the>; see also OIG, HHS Office of Inspector General Fact Sheet, Notice of Proposed Rulemaking OIG-0936-AA10-p (Oct. 2019), available at https://oig.hhs.gov/authorities/docs/2019/CoordinatedCare_FactSheet_October2019.pdf.

provided information regarding whether the proposals in the NPRM would effectively remove barriers to coordinated and value-based care and include the appropriate safeguards to protect Federal health care programs and patients.

The Final Rule

The Final Rule implements seven new safe harbors, modifies four existing safe harbors, and codifies one new exception under the Beneficiary Inducements CMP. The Final Rule modifies and clarifies the NPRM in response to comments and as explained in the preamble to the Final Rule. For example, the Final Rule clarifies how medical device manufacturers and durable medical equipment companies may participate in protected care coordination arrangements that involve digital health technology; lowers the level of “downside” financial risk parties must assume to qualify under the new safe harbor for value-based arrangements with substantial downside financial risk; and, in recognition of the urgent problem of cyber threats to the health care industry, broadens the new safe harbor for cybersecurity technology and services to cover remuneration in the form of cybersecurity-related hardware.

To safeguard against inappropriate incentives, the Final Rule incorporates additional limitations on parties seeking safe harbor protection under the patient engagement and support safe harbor, such as a fixed dollar cap on protected tools and supports provided to patients and enhanced restrictions on marketing and patient recruitment. As proposed, certain categories of entities that are not typically on the front lines of care coordination and pose a higher risk of fraud or abuse, such as pharmaceutical manufacturers and compounding pharmacies, are ineligible to use the new safe harbors for value-based arrangements, outcomes-based payments, and patient engagement and support. [Click here for more information about ineligible entities under these safe harbors.](#) Ineligible entities may be able to use other new or modified safe harbors if an arrangement satisfies all applicable conditions.

Subject to definitions and conditions set forth in the regulations in the Final Rule, the final safe harbor regulations protect:

- *Value-Based Arrangements.* Three 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 new safe harbors vary by the type of remuneration protected, level of financial risk assumed by the parties, and safeguards included as safe harbor conditions.

- *Patient Engagement and Support.* A 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 new safe harbor (§ 1001.952(ii)) for certain remuneration provided in connection with a CMS-sponsored model (as defined in the Final Rule), which should reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models.
- *Cybersecurity Technology and Services.* A new safe harbor (§ 1001.952(jj)) for donations of cybersecurity technology and services.

- *Electronic Health Records Items and Services.* 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.* Modifications to the existing safe harbor for personal services and management contracts (§ 1001.952(d)) to add flexibility for certain outcomes-based payments and part-time arrangements.
- *Warranties.* 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.* 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 an inpatient facility or released from a hospital after being placed in observation status for at least 24 hours.
- *Accountable Care Organization (ACO) Beneficiary Incentive Programs.* Codification of the statutory exception to the definition of “remuneration” under the anti-kickback statute related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (§ 1001.952(kk)).

Subject to definitions and conditions set forth in the regulations in the Final Rule, the final exception regulations under the Beneficiary Inducements CMP protect:

- *Telehealth for In-Home Dialysis.* An amendment to the definition of “remuneration” in the CMP rules at 42 C.F.R. § 1003.110 interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for “telehealth technologies” furnished to certain in-home dialysis patients.

Readers are directed to the [Final Rule for the regulations](#) we are finalizing and further explanation of the regulations.