HHS Office of Inspector General Fact Sheet

Notice of Proposed Rulemaking OIG-0936-AA10-P
October 2019

Background

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) is publishing a Notice of Proposed Rulemaking, **"Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements."** This proposed rule is part of HHS's Regulatory Sprint to Coordinated Care (Regulatory Sprint), which aims to reduce regulatory barriers and accelerate the transformation of the healthcare 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) for beneficiary inducements, 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 among providers and 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 the referral of business reimbursable under any of the Federal health care programs, including Medicare and Medicaid. Healthcare 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 any anti-kickback statute enforcement action (*see* 42 CFR § 1001.952). Parties may use any applicable safe harbor into which they can squarely fit. However, failure to fit in a safe harbor does not mean that an arrangement violates the 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 criminal intent. Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the healthcare industry.

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

In response to an August 2018 Request for Information, OIG received 359 responses from a range of stakeholders. OIG also coordinated with the Centers for Medicare & Medicaid Services (CMS), which is issuing a proposed rule in connection with the Regulatory Sprint.

The Proposals

The proposed rules are designed to promote coordinated patient care and foster improved quality, better health outcomes, and improved efficiency. The proposed safe harbors also include multiple proposed safeguards to protect against fraud and abuse. Readers are directed to the proposed rule for a complete description of the proposals.

Subject to definitions and conditions in the proposed regulations, the proposed changes include:

- *Value-Based Arrangements*. Three proposed 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 proposed safe harbors vary by the types of remuneration protected, level of financial risk assumed by the parties, and types of safeguards included as safe harbor conditions.
- *Patient Engagement*. A proposed 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 proposed new safe harbor (§ 1001.952(ii)) for certain remuneration provided in connection with a CMS-sponsored model (as defined in the proposed rule), which should reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models.
- *Cybersecurity Technology and Services*. A proposed new safe harbor (§ 1001.952(jj)) for donations of cybersecurity technology and services.
- *Electronic Health Records Items and Services*. Proposed 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*. Proposed modifications to the existing safe harbor for personal services and management contracts (§ 1001.952(d)) to add flexibility with respect to outcomes-based payments and part-time arrangements.
- *Warranties*. Proposed 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*. Proposed 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 inpatient facilities.
- *Accountable Care Organization (ACO) Beneficiary Incentive Programs*. Codification of the statutory exception to the definition of "remuneration" related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (§ 1001.952(kk)).
- *Telehealth for In-Home Dialysis*. A proposed 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.

OIG is soliciting public comments on a wide range of topics. Comments are due 75 days from the date of publication of the Notice of Proposed Rulemaking in the *Federal Register*. For further information and to access the proposed rule, please visit**:** https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp