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Proposed Anti-Kickback Statute Changes: Healthcare Valuation Implications

On October 9, 2019, the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) issued proposed rules to modernize and clarify the *Anti-Kickback Statute* (AKS).[1] The proposed rule changes were published in conjunction with the *Centers for Medicare & Medicaid Services* (CMS), which proposed rule changes to the *Stark Law*, and are part of the larger effort by HHS to modernize and clarify fraud and abuse laws as part of the *Regulatory Sprint to Coordinated Care* initiative[2] and CMS's *Patients over Paperwork* initiative.[3] The initiatives are aimed at reducing regulatory barriers and accelerating the transformation of the healthcare system into one that better pays for value and promotes care coordination.[4] Recognizing the rapidly changing healthcare system, CMS and OIG are proposing new rules, and rule changes, that are more consistent with emerging *value-based* healthcare delivery and payment models, and which may allow for better coordination of care.[5]

This *Health Capital Topics* article will summarize the AKS proposed rule, and review the new safe harbors proposed by HHS, as well as modifications to existing safe harbors.

The AKS "*provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration [directly or indirectly] to induce or reward the referral of business reimbursable under Federal health care programs*."[6] [Emphasis added.] AKS violations are punishable by up to five years in prison, criminal fines up to $25,000, or both.[7] Similar to the Stark Law, the AKS contains several *safe harbors*, which may shield an arrangement from regulatory liability if some or all of the requisite criteria is met.[8]

The OIG's proposed changes to the AKS are intended to promote coordinated care and foster improved quality, better health outcomes, and improved efficiency.[9] Among the more notable proposals related to the AKS include new safe harbors related to:

(1) *Value-Based Arrangements* – The OIG proposed three new safe harbors, aligned with those proposed by CMS (other than some formatting differences), for remuneration exchanged among participants in value-based arrangements that foster better coordinated and managed patient care:

   (a) Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency;

   (b) Value-Based Arrangements with Substantial Downside Financial Risk; and,

   (c) Value-Based Arrangements with Full Financial Risk.[10]

   These safe harbors vary by the types of remuneration protected, the level of financial risk assumed by the parties, and the types of safeguards included as safe harbor conditions.

(2) *Patient Engagement* – The OIG proposed a new safe harbor for certain tools and supports (not gift cards, cash, or cash equivalents) furnished to patients to improve quality, health outcomes, and efficiency. Such items may include:

   (a) Health-related technology patient health-related monitoring tools and services, such as smart watches and other wearable monitoring devices; and,

   (b) Supports and services designed to identify and address a patient's social determinants of health.[11]

(3) *CMS-Sponsored Models* – The OIG proposed a new, standardized safe harbor for all payment models sponsored by CMS through the Innovation Center, negating the need for separate fraud and abuse waivers currently in place on an arrangement-by-arrangement basis.[12]

(4) *Cybersecurity Technology and Related Services* – The OIG proposed a new *safe harbor* protecting the donation of cybersecurity technology and services subject to five conditions, including that the agreement be set forth in writing and that the donation (or receipt thereof) does not directly take into account the volume or value of referrals or other business between the parties.[13]

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Additionally, the OIG proposed modifying the following safe harbors currently in place:

(1) *Personal Services and Management Contracts and Outcomes-Based Payment Arrangements* – Modified to add more flexibility, e.g., by adding protections to certain outcomes-based payments.[14] Notably, OIG also proposed eliminating the requirement that aggregate compensation under these agreements be set in advance, instead requiring that the compensation *methodology* be set in advance; however, that methodology must be consistent with *Fair Market Value* and not be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties.[15]

(2) *Warranties* – Revises the definition of "*warranty*" and provides protection for bundled warranties for one or more items and related services.[16]

(3) *Local Transportation* – Expands mileage limits for rural areas and eliminates limits for patient transportation from the facility from which the patient is discharged to their home, as well as provides guidance related to ride-sharing services.[17]

(4) *Accountable Care Organization (ACO) Beneficiary Incentive Programs* – Codifies the statutory exception to the definition of "*remuneration*" as relates to ACO incentive payments to Medicare fee-for-service beneficiaries under the ACO Beneficiary Incentive Program, with some revisions.[18]

The proposed rule changes from the OIG, many of which changes are in alignment with those proposed by CMS in relation to the Stark Law, provide much greater certainty for healthcare providers participating in *value-based* arrangements and who are coordinating care for patients.[19] Additionally, the OIG attempted to ensure that, while reducing the burden of regulatory compliance, strong safeguards against fraud and abuse were maintained.[20]

As noted in the *Health Capital Topics* companion article in this month's issue related to the Stark Law proposed rule, the new and modified AKS safe harbors are applicable only to those arrangements that fall under the purview of the AKS, and, as noted by the agencies, OIG's AKS proposals may be more restrictive than CMS's due to the nature of the law, i.e., AKS is a criminal, intent based statute, and the Stark Law is a civil, strict liability law. Further, some AKS safe harbors (e.g., value based arrangements) differ from Stark Law exceptions. In both instances, healthcare providers will need to ensure compliance with either, or both, laws, depending on each law's applicability to the arrangement.

HCC will continue to closely monitor and report, in future *Health Capital Topics*, the progression of these fraud and abuse law reforms, as well as the implications of these prospective changes on transactions involving healthcare enterprises, assets, and services.

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1 "HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care" U.S. Department of Health & Human Services, October 9, 2019, https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html (Accessed 10/25/19).

2 "Notice of Proposed Rulemaking OIG-0936-AA10-P: Fact Sheet" HHS Office of Inspector General, October 2019, https://oig.hhs.gov/authorities/docs/2019/CoordinatedCare_FactSheet_October2019.pdf (Accessed 10/22/19), p. 1.

3 "Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule" U.S. Centers for Medicare & Medicaid Services, October 9, 2019, https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-proposed-rule (Accessed 10/22/19).

4 HHS Office of Inspector General, October 2019; U.S. Centers for Medicare & Medicaid Services, October 9, 2019.

5 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55835; U.S. Centers for Medicare & Medicaid Services, October 9, 2019.

6 "Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP" Federal Register, Vol. 83, No. 166 (August 27, 2018), p. 43607.

7 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1) (2013).

8 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, http://oig.hhs.gov/fraud/docs/advisoryopinions/15/AdvOpn15-10.pdf (Accessed 9/23/19), p. 5; Federal Register, Vol. 64, No. 223 (November 19, 1999), p. 63518-63520.

9 "Notice of Proposed Rulemaking OIG-0936-AA10-P: Fact Sheet" HHS Office of Inspector General, October 2019, https://oig.hhs.gov/authorities/docs/2019/CoordinatedCare_FactSheet_October2019.pdf (Accessed 10/27/19), p. 2.

10 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55700.

11 *Ibid*, p. 55724.

12 *Ibid*, p. 55730.

13 *Ibid*, p. 55733-55739.

14 *Ibid*, p. 55744-55745).

15 *Ibid*, p. 55747.

16 *Ibid*, p. 55748-55749.

17 *Ibid*, p. 55750.

18 *Ibid*, p. 55752.-55753.

19 "HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care" U.S. Department of Health & Human Services, October 9, 2019, https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html (Accessed 10/21/19).

20 *Ibid*.

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