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# HHS OIG's 13 New FAQs Shed Light on Post-Public Health Emergency Enforcement

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On March 22, 2023, the U.S. Department of Health and Human Services' Office of Inspector General ("OIG") updated its Frequently Asked Questions ("FAQs"), drafting 13 FAQs aimed at easing the transition from COVID-era flexibilities to the end of the Public Health Emergency ("PHE") on May 11, 2023. These FAQs arrive on the tail of OIG's March 10, 2023 COVID-19 Public Health Emergency policy statement, which announced that the expiration of the PHE in May also marks the end of flexibilities extended during the crisis. The updated FAQs offer a glimpse into how OIG investigations and enforcement might play out after the end of the PHE. These FAQs address subjects including "General Questions Regarding Certain Fraud and Abuse Authorities," the "Application of Certain Fraud and Abuse Authorities to Certain Types of Arrangements," and "Compliance Considerations."

The vast majority of the principles articulated in the updated FAQs will undoubtedly be familiar to many. Generally speaking, the updated FAQs restate or clarify longstanding OIG policy. The updated FAQs are more than reiteration, however; they offer condensed policy and explanation in a single location, and demonstrate that for the most part, investigations and enforcement may return to the pre-PHE status quo.

A point of departure is the guidance in the updated FAQs governing naloxone. Even though a hospital's provision of free naloxone upon discharge may implicate the Anti-Kickback Statute ("AKS") and the Beneficiary Inducements Civil Monetary Penalty ("CMP"), OIG described its provision, when certain factors are present, as a "sufficiently low risk of fraud and abuse," especially in light of the drug's role in reducing overdose deaths.

Worth noting is that the day after OIG's publication of the updated FAQs, Robert DeConti, Chief Counsel of the Inspector General, speaking at the AHLA's Institute on Medicare and Medicaid Payment Issues, offered a few related thoughts. Although Mr. DeConti described the advantage of the updated FAQs as providing an opportunity for OIG to quickly answer questions, he cautioned that the FAQs do not replace the Advisory Opinion process and, accordingly, do not confer prospective immunity. Mr. DeConti encouraged those in the industry to submit further questions. As May 11 grows closer, we can expect further clarity through industry participation in the FAQ process.

## The Flexibilities Ending May 11, 2023: Telehealth, Stark, and Anti-Kickback

The flexibilities expiring with the end of the PHE were outlined by OIG in two policy statements and an FAQ.

The first policy statement, from March of 2020, pertained to telehealth: it informed practitioners that they would not be subject to administrative sanctions for waiving or reducing cost-sharing obligations that beneficiaries owed for telehealth services.[1]

The second policy statement, from April of 2020, stated that OIG would not impose certain administrative sanctions for types of remuneration related to Blanket Waivers of Section 1877(g) of the Social Security Act.[2] Notably, Stark Law blanket waivers exempted over a dozen types of remuneration and referrals.

The FAQ, also from April of 2020, clarified that although OIG issued no such AKS waiver, it would not impose administrative sanctions on arrangements that satisfied the Stark Law blanket waivers.[3]

## Summary of March 22, 2023 FAQs

The following is a brief summary of the March 22, 2023 FAQs:

***General Questions Regarding Certain Fraud and Abuse Authorities***

(1) Preliminarily, OIG draws a bright line between arrangements that satisfy an AKS safe harbor and those that do not. The satisfaction of part of an AKS safe harbor's conditions will not pass muster—compliance requires satisfaction of **all** conditions.

(2) The Beneficiary Inducements Civil Monetary Penalty ("CMP") is distinguished from the AKS. First of all, the CMP is narrower: it applies to Medicare, Medicaid, and CHIP (vs. the AKS's applicability to any Federal Healthcare Program); the CMP also defines "remuneration" differently; it applies only to the person offering the remuneration (vs. the AKS's applicability to those offering and those soliciting or receiving); and it applies to remuneration likely to influence a beneficiary's choice of provider or supplier (vs. the AKS's broad prohibition on remuneration for referrals "to a person for the furnishing" of a good or service, and purchases of "any good, facility, service or item").

(3) OIG clarifies that an arrangement that satisfies the exceptions to the Beneficiary Inducements CMP is not also protected under the AKS, but an exception under the AKS *is* protected under the Beneficiary Inducements CMP.

(4) OIG also distinguishes exceptions of the physician self-referral law (42 U.S.C. § 1395nn) ("Stark Law") from AKS exceptions. In short, compliance with the former does not rebut the implication of intent under the latter.

(5) OIG discusses the differences and distinctions between "cash," "cash equivalents," and "in-kind" gift cards. "Cash" refers to currency; "cash equivalents" are items convertible to cash, such as checks or prepaid Visa or Mastercard gift cards; and "in-kind" gift cards are those redeemed only for certain types of services or items (such as a meal delivery service or gasoline). Note that OIG cautions that Centers for Medicare & Medicaid Services (CMS) may have their own take on these terms.

(6) As to whether arrangements between Electronic Health Records ("EHR") vendors and their

customers implicate the AKS, OIG clarifies: "possibly." For the AKS to be implicated, a part of or the whole EHR product would have to be reimbursable under a Federal Healthcare Program.

(7) Noting the shift from fee-for-service toward value-based care, OIG addresses whether remuneration exchanged among entities with common ownership implicates the AKS. OIG references a 2020 final rule setting out safe harbors for value-based arrangements,[4] and notes that the Advisory Opinion process is available for further clarification on any particular arrangement.

(8) With regard to ambulatory surgical center (ASC) safe harbors and investment interests, OIG states that it considers several factors when ASC physician investments do not satisfy the Practice Income Test: (i) whether the physician-investor refers patients to the ASC for procedures he or she will not personally perform; (ii) whether the physician-investor uses the ASC for his or her own procedures, and (iii) the circumstances that led the physician-investor to fail the Practice Income Test.

(9) Finally, the FAQs provide a link to the Annual Inflation Updates to the Annual Cap on Patient Engagement Tools and Supports Under 42 CFR § 1001.952(hh).

***Application of Certain Fraud and Abuse Authorities to Certain Types of Arrangements***

(1) OIG addresses whether a hospital can distribute to patients, upon discharge, free naloxone rescue kits. The provision of free items of value—including such kits—to Federal Healthcare Program beneficiaries, who could ostensibly self-refer to the hospital for reimbursable services and items, implicates the AKS. However, given the exigencies of the opioid epidemic, OIG notes that providing naloxone in like circumstances presents a low risk of fraud while potentially saving lives. OIG suggests four ways to reduce the risk of fraud: (i) compliance with all other Federal and State laws governing naloxone distribution; (ii) having a written policy for the distribution of naloxone kits to at-risk patients, and applying that policy uniformly to all patients who present at the emergency department; (iii) not advertising the rescue kits to induce a beneficiary to receive federally reimbursable items or services; (iv) ensuring that the provision of free naloxone kits is not contingent on a beneficiary's selection of the hospital for future reimbursable care or services.

(2) OIG also states that remuneration to a Dual Eligible Special Needs Plan (D-SNP) enrollee for serving on the plan's enrollee advisory committee would probably not implicate the Beneficiary Inducements CMP, although it could implicate the AKS. OIG discusses a few factors that could reduce the risk of violating the AKS: (i) remuneration of modest value and proportionate to the committee member's time; (ii) using a selection process based on factors unrelated to an enrollee's health "to avoid cherry-picking"; and (iii) not advertising the remuneration associated with the committee position.

***Compliance Considerations***

(1) When considering exclusion, OIG explains how the agency assesses future risk to Federal Healthcare Programs and their beneficiaries: through criteria published on April 18, 2016.[5]

(2) When assessing the "level of fraud and abuse risk posed by an arrangement" implicating the AKS, OIG considers a number of factors set out by Congress, which are reiterated by OIG's Compliance Program Guidance.[6] From that guidance, the FAQ reiterated a five-question test for whether an arrangement is problematic:

1. Does the arrangement or practice have the potential to interfere with, or skew, clinical decision making?

2. Does the arrangement or practice have the potential to increase costs to Federal health care programs or beneficiaries?

3. Does the arrangement or practice have the potential to increase the risk of overutilization or inappropriate utilization?

4. Does the arrangement or practice raise patient safety or quality of care concerns?

5. Does the arrangement or practice raise concerns related to steering patients or providers to a particular item or service?

**FOOTNOTES**

[1] https://oig.hhs.gov/documents/special-advisory-bulletins/960/policy-telehealth-2020.pdf

[2] https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf

[3] https://oig.hhs.gov/coronavirus/authorities-faq.asp

[4] 85 Fed. Reg. 77,684 (Dec. 2, 2020); https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf

[5] https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf

[6] https://oig.hhs.gov/documents/compliance-guidance/799/050503FRCPGPharmac.pdf



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