



U.S. Department of Health & Human Services
Office of Inspector General

HCCA Virtual Conference Healthcare Enforcement Compliance Conference

November 16, 2020

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1. Federal Anti-Kickback Statute:
Real-World Hypotheticals
2. OIG's Work to Meet COVID-19
Strategic Goals
3. HHS Regulatory Sprint to
Coordinated Care

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Agenda



Federal Anti-Kickback Statute: Real-World Hypotheticals

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Quick Refresher: Federal Anti-Kickback Statute

Prohibits the **knowing and willful** offer, payment, solicitation or receipt of **remuneration**, directly or indirectly, **in return for** referring an individual for, or purchasing, leasing, ordering (or recommending or arranging for the purchasing, leasing, or ordering) of **items or services** covered by a Federal health care program

42 U.S.C. § 1320a-7b(b)

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Federal Anti-Kickback Statute: Key Points



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Exceptions and Safe Harbors to Federal Anti-Kickback Statute

- Statutory exceptions
- Regulatory safe harbors
- Voluntary
- See 42 CFR § 1001.952

Examples



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Quick Refresher: Beneficiary Inducements CMP

Prohibits offers or transfers of **remuneration** to any individual eligible for benefits under Medicare or State health care program that such person **knows or should know** is **likely to influence** such individual to order or receive from a **particular provider, practitioner, or supplier** any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program.

42 U.S.C. § 1320a-7a(a)(5)

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Beneficiary Inducements CMP: Exceptions

- Voluntary
- Regulatory exceptions (42 C.F.R. § 1003.110)
- AKS safe harbors apply (42 U.S.C. § 1320a-7a(i)(6)(B))
 - But the reverse is not true

Examples

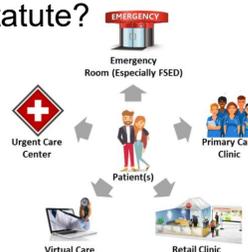


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Hypo # 1 – Post-Acute Provider Network

- A hospital would like to form a preferred (post-acute) provider network
- In connection with this preferred provider network, the post-acute provider would provide care coordinators, social workers, and “charity care” days to the hospital
- Does this arrangement implicate the anti-kickback statute?
- Any available safe harbors?
- Impact of participation in CMS- or payor-sponsored model?



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Hypo # 2 – Providers Supporting Patients

- A hospital would like to provide specific supports to patients that satisfy certain clinical criteria (e.g., patients with congestive heart failure, patients with chronic obstructive pulmonary disease, patients requiring an organ transplant)
- The supports include:
 - Home safety assessments
 - Post-discharge medication reviews
 - Transportation to follow-up appointments
 - Free or reduced-cost lodging and meals
- Does this provision of supports implicate the anti-kickback statute? The beneficiary inducements CMP?
- Do any safe harbors or exceptions exist?



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Hypo # 3 – Health System Offering Free Ride-Sharing to Patients

- Health system partners with ride-sharing service (e.g., Uber, Lyft) to transport patients to medical appointments
- Health system offers a website that allows patients schedule their own rides
- Does this provision of supports implicate the anti-kickback statute? The beneficiary inducements CMP?
- Do any safe harbors or exceptions exist?
- Any additional considerations?

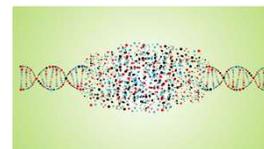


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Hypo # 4 – Manufacturer-Supplied Travel, Lodging, and Meals to Patients Receiving Personalized Medicine Treatment

- Drug manufacturer provides travel, lodging, and meals to FHCP beneficiaries during drug treatment and for approximately four weeks following treatment
- Drug is subject to REMS with ETASU, so administration is limited to certain facilities approved by the manufacturer
- Additional factual details:
 - Patients must reside at least 100 miles or more than two hours driving distance from an approved facility
 - Free travel, lodging, and meals are designed to mitigate patient harm from potentially lethal drug side effects and to promote following the drug's prescribing information
 - Patients must meet financial need criteria
 - Drug use must be on-label

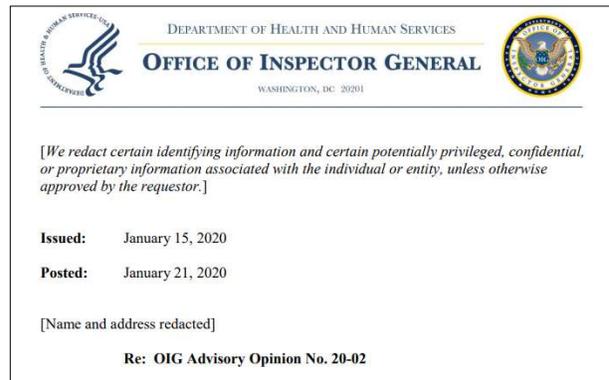


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Hypo # 4 (continued) – Manufacturer-Supplied Travel, Lodging, and Meals to Patients Receiving Personalized Medicine Treatment

- Does this provision of free travel, lodging, and meals implicate the anti-kickback statute? The beneficiary inducements CMP?
- Do any safe harbors or exceptions exist?



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Hypo # 5 – Providing Free Smartphones to Patients

- Drug manufacturer loans limited-functionality smartphones to patients in order to facilitate collection of medication adherence data from an ingestible sensor embedded in medication tablet
- Patients must meet financial need criteria and must not already have access to the necessary technology
- Nonadherence or partial adherence to the drug regimen results in higher utilization of health care services and increased costs to the health care system

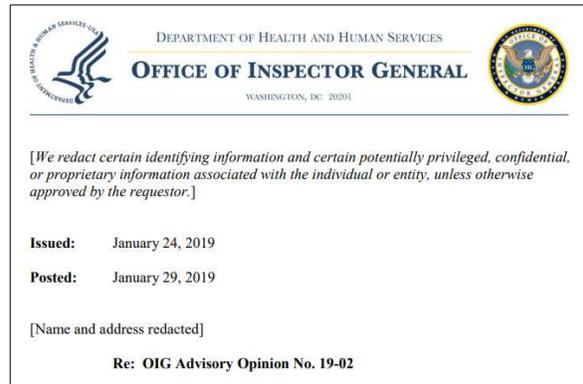


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Hypo # 5 (continued)– Providing Free Smartphones to Patients

- Does this provision of a free loaner smartphone implicate the anti-kickback statute? The beneficiary inducements CMP?
- Do any safe harbors or exceptions exist?



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Hypo # 5A – Providing Free Smartphones to Patients

- Mental health and substance abuse provider gives free smartphone to patients in order to facilitate treatment in lieu of in-person treatment during the COVID-19 pandemic
- Does this provision of a free smartphone implicate the anti-kickback statute? The beneficiary inducements CMP? Do any safe harbors or exceptions apply?

FAQs–Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Last Updated: 09-03-2020

The Office of Inspector General (OIG) recognizes that, in the current public health emergency resulting from the outbreak of the COVID-19, the health care industry must focus on delivering needed patient care.¹ As part of OIG's mission to promote economy, efficiency, and effectiveness in HHS programs, we are committed to protecting patients by

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OIG's Work to Meet COVID-19 Strategic Goals

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OIG's COVID-19 Strategic Goals

Protect People

- A. Assist in and support ongoing COVID-19 response efforts, while maintaining independence
- B. Fight fraud and scams that endanger HHS beneficiaries and the public
- C. Assess the impacts of HHS programs on the health and safety of beneficiaries and the public

Protect Funds

- A. Prevent, detect, and remedy waste or misspending of COVID-19 response and recovery funds
- B. Fight fraud and abuse that diverts COVID-19 funding from intended purposes or exploits emergency flexibilities granted to health and human services providers

Protect Infrastructure

Protect the security and integrity of IT systems and health technology

Promote Effectiveness

- A. Support the effectiveness of Federal, State, and local COVID-19 response and recovery efforts
- B. Leverage successful practices and lessons learned to strengthen HHS programs for the future

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Waiving Telehealth Cost-Sharing

- In March, OIG issued “OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services”
- Telehealth FAQ



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak
March 17, 2020

FAQs—OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak
As of March 24, 2020

On March 17, 2020, OIG issued “OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak” (the Policy Statement).¹ Since the issuance of the Policy Statement, OIG has received questions regarding the scope of the Policy Statement. OIG’s responses to frequently asked questions related to the Policy Statement are below. As OIG states in the Policy Statement, OIG is committed to protecting patients by ensuring that healthcare providers have the regulatory flexibility necessary to adequately respond to COVID-19 concerns. We will update this document if we receive additional frequently asked questions related to the Policy Statement.

1. Does the Policy Statement apply to services provided remotely through information or communication technology, or is the Policy Statement limited to the specific services the Centers for Medicare & Medicaid Services (CMS) refers to as “telehealth visits”?

OIG’s Policy Statement is not limited to the services governed by 42 C.F.R. § 410.78 and referred to by CMS as “telehealth visits.” OIG intends for the Policy Statement to apply to a broad category of non-face-to-face services furnished through various modalities, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring.

2. Many physicians and other practitioners are organized within larger healthcare provider entities and systems. Does the Policy Statement apply to a hospital, for example, when a physician or other practitioner who has reassigned his or her right to receive payments to the hospital provides services remotely through information or communication technology?

The Policy Statement applies to a physician or other practitioner billing for services provided remotely through information or communication technology or a hospital or other eligible

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Policy Statement on Administrative Enforcement Authorities

- CMS issued “Blanket Waivers” of the Physicians Self-Referral Law
- “OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities”
 - OIG will not impose administrative sanctions for certain conduct identified in CMS Blanket Waivers
 - Only applies to section II.B.(1)-(11) of Blanket Waivers
 - FAQ addressing scope of Policy Statement
- Examples of protected conduct

Blanket Waivers of Section 1877(g) of the Social Security Act
Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency
Effective March 1, 2020

I. Preamble

Section 1135 of the Health and Human Services (HHS) Act of 1996 requires waiver authority. If the Secretary determines that a health emergency exists, the Secretary may waive the application of section 1135(b) of the Act if the Secretary determines that such waiver is necessary in the interest of the health and safety of the people.

Under section 1135 of the Act, the Secretary may, in any emergency, suspend or waive the application of any provision of the Medicare, Medicaid, and Supplemental Medical Insurance Act, or any regulation issued under the Act, if the Secretary determines that such suspension or waiver is necessary in the interest of the health and safety of the people.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency
April 3, 2020

On January 31, 2020, the Secretary issued a determination, pursuant to section 319 of the Public Health Service Act, that a public health emergency resulting from the outbreak of the novel coronavirus disease 2019 (COVID-19) exists and has existed since January 27, 2020 (COVID-19 Declaration).¹ In response to the unique circumstances resulting from the COVID-19 outbreak

Why does the “OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency” not incorporate sections II(B)(12)-(18) of the blanket waivers of the physician self-referral law as issued by the Secretary?

Posted May 1, 2020

The “OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency” does not incorporate sections II(B)(12)-(18) of the blanket waivers of the physician self-referral law as issued by the Secretary. Sections II(B)(12)-(17) of the [blanket waivers](#) of the physician self-referral law protect “referrals,” as defined under section 1877(g) of the Act, rather than “consultations,” and reflect differences in the statutory provisions of the

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COVID-19 FAQs

- “FAQs—Application of OIG’s Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency”
- Since April, OIG has issued 13 FAQs
- Examples:
 - Free COVID-19 antibody testing
 - In-kind transportation assistance for oncology care
 - Free access to a web-based telehealth platform



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COVID-19 FAQ Example: Home Health Agency Offers Free Blood Draws to Assisted Living Residents

Can a home health agency's (HHA) staff members furnish free blood draws provided that such blood draws are within the scope of the staff's licenses to assisted living facility residents who are Federal health care program beneficiaries and are not patients of the HHA?

Posted September 3, 2020

OIG's longstanding guidance makes clear that, depending on the facts and circumstances, the provision of free goods or services to an actual or potential referral source of Federal health care program business may implicate the Federal anti-kickback statute. Similarly, the provision of free goods or services to a patient of a referral source may implicate the Federal Beneficiary Inducements Code. However, in light of the unique circumstances resulting from the COVID-19 outbreak, we believe that the provision of free blood draws to assisted living facility beneficiaries residing in an assisted living facility may improve access to care and promote patient safety during the current pandemic by avoiding exposure to a separate testing site.

“Facilitating blood draws for medically necessary clinical laboratory testing in a patient's residence may improve access to care and promote patient safety during the current pandemic by avoiding exposure to a separate testing site.”

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COVID-19 Portal

This page was last updated November 9, 2020.

Fraud Alert Current Infectious Disease Work Policies & Guidance

<https://oig.hhs.gov/coronavirus>

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HHS Regulatory Sprint to Coordinated Care

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Status of the Final Rules

- <https://www.reginfo.gov/public/do/eoReviewSearch>

AGENCY: HHS-OIG	RIN: 0936-AA10	Status: Pending Review
TITLE: Revisions to the Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalties Rules Regarding Beneficiary Inducement		
STAGE: Final Rule	ECONOMICALLY SIGNIFICANT: No	
RECEIVED DATE: 07/21/2020	LEGAL DEADLINE: None	

AGENCY: HHS-CMS	RIN: 0938-AT64	Status: Pending Review
TITLE: Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720)		
STAGE: Final Rule	ECONOMICALLY SIGNIFICANT: No	
RECEIVED DATE: 07/21/2020	LEGAL DEADLINE: Statutory	

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Regulatory Sprint Proposed Rule: A Roadmap

- **Proposed value-based arrangements safe harbors**
 - Value-based care terminology
 - Care coordination arrangements to improve quality, health outcomes, and efficiency
 - Value-based arrangements with substantial downside financial risk
 - Value-based arrangements with full financial risk
- **Proposed patient engagement and support safe harbor**
 - Incorporates key value-based care terminology
- **Proposed CMS-sponsored model arrangements safe harbor**
- **Proposed cybersecurity technology and services safe harbor**

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Regulatory Sprint Proposed Rule: A Roadmap (continued)

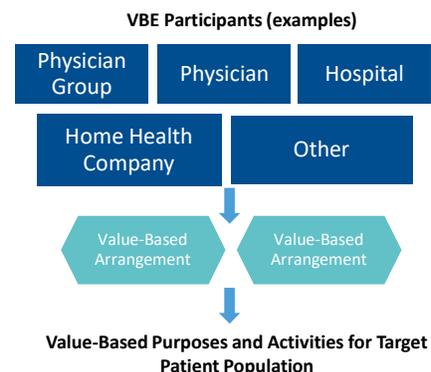
- **Proposed modifications to existing safe harbors**
 - Personal services and management contracts (outcomes-based payments)
 - Warranties (narrow expansion)
 - Local transportation (adjust mileage limitations)
 - EHR (update provisions regarding interoperability, remove the sunset date)
- **Proposed ACO Beneficiary Incentive Program safe harbor**
- **Proposed exception for telehealth technologies for in-home dialysis** (beneficiary inducements CMP exception)

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Value-Based Framework (as proposed)

- Value-based enterprise (VBE)
- Value-based purpose
- Coordination and management of care
- VBE participant
- Value-based activities
- Value-based arrangement
- Target patient population



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Questions?