

Beneficiary Inducement and False Claims Act

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Overview

The Laws

- Civil Monetary Penalties Law
- Anti-Kickback Statute
- Eliminating Kickback in Recovery Act
- False Claims Act

Applying the Laws to Common Situations

- Free or discounted items or services
- Items of low value
- Free tests or screening
- Free transportation
- Waiving copays and deductibles
- Writing off bill
- Professional courtesies
- Prompt pay or self-pay discounts
- Paying patient premiums
- Others?

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Scope of Discussion

- We will be focusing on **federal statutes** re inducements **government program beneficiaries**.
- Additional or laws or limitations may apply in these or other cases, including private pay situations, *e.g.*,

State Laws

- Anti-kickback statutes
- Rebates or inducements
- Waiving copays or deductibles
- Bribery
- Unfair trade practices
- Others?

Don't forget
to consider
these...

Payor contracts

- Requirement to collect copays and deductibles
- Requirements to bill insurer for services
- Prohibition on inducements to insureds
- Others?

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Overview



BENEFICIARY INDUCEMENT LAW



FALSE CLAIMS ACT
 ANTI-KICKBACK STATUTE
 ELIMINATING KICKBACK IN RECOVERY ACT

Prohibits:

- Paying (or offering to pay) OR receiving (or soliciting)
- Any remuneration – direct/indirect, cash/kind
- To or from anyone
- To induce the purchase/order
- Of items/services
- Reimbursed by a govt health care program (Medicare/Medicaid)

- ✓ Whistleblower / Qui Tam Provisions
- ✓ Treble Damages + Fines
- ✓ ACA Revisions: AKS → FCA

| Anti-Kickback Statute | |
|----------------------------------|--|
| Criminal offense | <ul style="list-style-type: none"> • Two-way street • Remuneration: broad definition • “One purpose” • Federal health care programs |
| Penalties | <ul style="list-style-type: none"> • Criminal (\$100K; 10 years) • Civil (Treble damages; \$50K) |
| Exceptions / Safe Harbors | <ul style="list-style-type: none"> • Statutory Exceptions • Regulatory Safe Harbors [Personal Services, etc.] |
| Risk Factors | <ul style="list-style-type: none"> • Costs to fed govt? Over-utilization? • Quality of Care? Access to Care? • Freedom of choice? • Independent judgment? • Limiting Competition? |

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Beneficiary Inducements Civil Monetary Penalty

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Beneficiary Inducements Civil Monetary Penalty

Section 1128(A)(5) of the Social Security Act, 42 U.S.C. § 1320a-7a(a)(5):

- Any person who offers or transfers
- remuneration
- to a Medicare or Medicaid beneficiary
- that the person knows or should know
- is likely to influence the beneficiary's selection of
- a particular provider, practitioner, or supplier of
- Medicare or Medicaid payable items or services may be liable for CMP's of up to \$10,000 per wrongful act

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When Is the Beneficiary Inducements CMP Implicated?

Are Medicare or Medicaid patients included?

Is the proposed inducement greater than “nominal value”?

Is the proposed inducement “likely to influence” provider?

Is one purpose to induce beneficiary selection of covered provider?

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What Is Remuneration Under the Beneficiary Inducements CMP?



AND furnishing items and services for free or below fair market value

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Beneficiary Inducements CMP: Exceptions

- **42 CFR § 1003.110 (definition of remuneration) exceptions:**
 - Coinsurance/Deductible Waivers if conditions are met
 - Practices Permissible Under AKS Safe Harbors
 - Retailer Rewards
 - Incentives to Promote the Delivery of Preventive Care
 - Any Other Remuneration which Promotes Access to Care AND Poses a Low Risk of Harm to Patients and Federal Health Care Programs
 - Part D Plan Co-Pay Waiver on First Fill Generics
 - Individual Financial Need-Based

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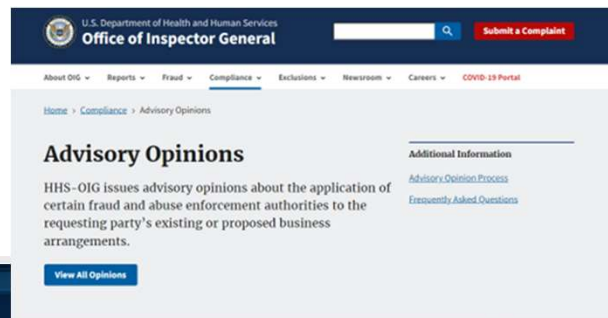
Selected OIG Guidance and Advisory Opinions

Selected OIG Guidance

- Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 58555 (Aug. 2002)
- Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016)

Selected Advisory Opinions

- Advisory Opinion No. 8-14 (Sept 24, 2008)
- Advisory Opinion No. 20-08 (Dec. 23, 2020)
- Advisory Opinion No. 22-04 (Feb. 25, 2022)



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Nominal Value Guidance

- **Congress intended to permit inexpensive gifts**
- **OIG Guidance:**
 - **No more than \$15 per item or \$75 in the aggregate per patient on an annual basis**
 - **No cash or cash equivalents**

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Why are Beneficiary Inducements Problematic?

- **Concerns over cost and quality**
 - Increases cost? – May encourage the use of medically unnecessary services
 - Lowers quality? – Will providers feel pressure to offset the additional costs attributable to the giveaway by providing cheaper/lower quality services?
- **Creates an unlevel playing field**
 - Only larger providers could afford inducements, creating disadvantages for smaller providers
- **Signals other compliance problems?**

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Anti-Kickback Statute

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Anti-Kickback Statute

“(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person-

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony”



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Anti-Kickback Statute Penalties

- **Penalties for AKS violations include:**
 - Up to 10 years in prison + up to \$100,000 fine for each violation for individuals
 - Administrative civil monetary penalties plus three times the amount of the remuneration paid
 - Suspension or exclusion from participation in federal and state health care programs
- **AKS violations may result in False Claims Act liability**
 - “[A] claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act].” 42 U.S.C. § 1320a-7b(g).



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Anti-Kickback Statute Sample Safe Harbors

- **Waiver of beneficiary copayment, coinsurance and deductible amounts**
 - Inpatient hospital services
 - Public Health Services Act
 - Pharmacies
 - Ambulances
- **Transportation**
 - Free or discounted local transportation (within 25 miles or 75 miles if a rural area)
- **Patient Engagement and Support**
 - Limited to certain VBE participants
 - In-kind items (not cash or cash equivalents)
 - Direct connection to the coordination and management of care of the target patient population;
 - Advances one or more of the specified goals

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Eliminating Kickback in Recovery Act

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Eliminating Kickback in Recovery Act (EKRA)

- Prohibits soliciting, receiving, paying or offering any remuneration in return for referring a patient to a laboratory, recovery home or clinical treatment facility unless arrangement fits within statutory or regulatory exception.

(18 USC § 220(a))

- “Laboratory” = facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing info for the diagnosis, prevention, or treatment of any disease or impairment of human beings.
- “Clinical treatment facility” = a medical setting, other than a hospital, that provides detox, risk reduction, outpatient treatment, residential treatment, or rehabilitation for substance use.

(18 USC § 220(e))

- *Beware any inducement for patients to order labs.*

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EKRA Penalties

- \$200,000 criminal fine
 - 10 years in prison
- (18 USC § 220(a))
- Applies to private or public payors.



CAUTION

Beware EKRA anytime you offer any inducements related to:

- Labs,
- SUD clinical treatment center, or
- Recovery home

The CMPL and AKS exceptions and our discussion below will generally not apply to EKRA or inducements relating to such services.

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EKRA Safe Harbors

- Payment to employee or independent contractor
- Discount under certain health care benefit programs.
- Waiver or discount of copays.
- Subsidies to health centers
- Remuneration under alternative payment models.
- Other situations approved in regulations.

(18 USC § 220(b))

- No regulatory safe harbors.

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False Claims Act

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False Claims Act

- Prohibits knowingly submit a false claim for payment to the federal govt, *e.g.*,
 - Not provided as claimed,
 - Substandard care, or
 - Failed to comply with applicable regulations.
- Must report and repay an overpayment within the later of 60 days or date cost report is due.
(31 USC § 3729; 42 USC §§ 1320a-7a(a) and 1320a-7k(d); 42 CFR §§ 401.305 and 1003.200)
- Overpayment = funds that a person receives or retains to which the person, after applicable reconciliation, is not entitled. (42 USC § 1320a-7k(d)(4))
- Overpayment includes situations in which claims are not payable, *e.g.*, a violation of the Anti-Kickback Statute. (81 FR 7658)

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False Claims Act Penalties

- Repayment plus interest
- Civil monetary penalties of \$11,803* to \$23,607* per claim
- Admin penalty \$22,427* per claim failed to return
- 3x damages
- Exclusion from Medicare/Medicaid
(42 USC § 1320a-7a(a); 42 CFR § 1003.210; 45 CFR § 102.3; 86 FR 70740)
- Potential *qui tam* lawsuits

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FOR IMMEDIATE RELEASE Tuesday, February 7, 2023

False Claims Act Settlements and Judgments Exceed \$2 Billion in Fiscal Year 2022
Second-Highest Number of Settlements in History

Settlements and judgments under the False Claims Act exceeded \$2.2 billion in the fiscal year ending Sept. 30, 2022, Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division, announced today. The government and whistleblowers were party to 351 settlements and judgments, the second-highest number of settlements and judgments in a single year. Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than \$72 billion.

"Protecting taxpayer dollars by preventing fraud and abuse is a critical priority for the Department of Justice," said Principal Deputy Assistant Attorney General Boynton. "The large number of settlements and judgments this past year demonstrates that the False Claims Act remains one of the most important tools for ensuring that public funds are spent properly and advance the public interest."

The False Claims Act imposes treble damages and penalties on those who knowingly and falsely claim money from the United States or knowingly fail to pay money owed to the United States. The False Claims Act thus serves to safeguard government programs and operations that provide access to medical care, support our military and first responders, protect American businesses and workers, help build and repair infrastructure, offer disaster and other emergency relief, and provide many other critical services and benefits.

Of the more than \$2.2 billion in False Claims Act settlements and judgments reported by the Department of Justice this past fiscal year, over \$1 billion related to matters that involved the health care industry, including drug and medical device

RELATED LINKS

- Speeches and Press Releases
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- Podcasts

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- We will be focusing on inducements to government program beneficiaries.
- Different rules may apply to private-pay patients, e.g.,
 - EKRA
 - State laws
 - Payer contracts
 - Others?

Applying the Law

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Free or Discounted Items or Services to Patients

- Gifts to patients (e.g., gift basket, gift card, basket of products for new mothers, etc.)
 - “Refer a friend” incentive
 - Free screening exam or service
 - Free equipment, supplies, or drugs
 - Free meals or lodging
 - Free transportation
 - Reward or incentive to comply with treatment
 - Parking reimbursement
 - Waiver or discount of copay or deductible
 - Write offs
 - Paying patient premiums
 - Anything else of value that does not reflect fair market value (“FMV”)
- Potential violations of
- AKS
 - EKRA
 - CMPL
 - State laws
 - Others?

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Free or Discounted Items or Services to Patients

May generally offer free or discounted items to govt beneficiaries if:

- **Remuneration is not likely to influence the patient 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 Medicaid.** (42 USC § 1320a-7a(a)(5); *see also* 81 FR 88394-95; Adv. Op. 22-16)
- “[I]ncentives that are not advertised or otherwise disclosed to a beneficiary before the beneficiary selects a provider for services do not come within the statutory prescription...” (65 FR 24409)
- **No intent to induce or reward referrals.** (42 USC § 1320a-7b)
- Remember “one purpose” test, *i.e.*, AKS is violated if “one purpose” of the remuneration is to induce or reward referrals unless fit within AKS safe harbor. (*See, e.g., United States v. Nagelvoort*, 856 F.3d 1117 (7th Cir. 2017); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985))

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Free or Discounted Items or Services to Patients

- May generally offer free or discounted items to govt beneficiaries if:

- **Item or service is of low value**, i.e.,
 - Each item or service is less than \$15, and
 - Aggregate is less than \$75 per patient per year.

(OIG Bulletin, *Offering Gifts and Inducements to Beneficiaries* (8/02); 66 FR 24410-11; *OIG Policy Statement Regarding Gifts of Nominal Value* (12/7/16))

- No similar rule AKS, but OIG has indicated that it would not challenge gifts of “nominal value.”

(See, e.g., *OIG Special Fraud Alerts* (2/94))

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Free or Discounted Items or Services to Patients

May generally offer free or discounted items to govt beneficiaries if:

- **Fit within an AKS exception or safe harbor**, e.g.,
 - Waiver of beneficiary copays, coinsurance and deductibles.
 - Local transportation.
 - Arrangements for patient engagement and support to improve quality, health outcomes and efficiency.
 - CMS-sponsored model patient incentives.
 - ACO beneficiary incentive programs.

(42 CFR § 1003.110, definition of “remuneration”; see also 42 USC § 1320a-7b(b) and 42 CFR § 1001.952)

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Free or Discounted Items or Services to Patients

May generally offer free or discounted items to govt beneficiaries if:

- **Demonstrated financial need**
 - Either (i) good faith determination that beneficiary has financial need or (ii) after reasonable collection efforts have failed;
 - Not offered as part of any advertisement or solicitation;
 - Not tied to provision of other federal program business; and
 - Reasonable connection between item or service and medical care of beneficiary.

(42 USC § 1320a-7a(i), definition of "remuneration"; 42 CFR § 1003.110, definition of "remuneration")

- Not cash or cash equivalent. (81 FR 88402)
- No corresponding AKS safe harbor but OIG has stated, "The Federal anti-kickback statute does not prohibit discounts to uninsured patients who are unable to pay their hospital bills." (OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills* (2/04))

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Free or Discounted Items or Services to Patients

May generally offer free or discounted items or services to govt beneficiaries if:

- **Promotes access to items or services payable by Medicare/ Medicaid** (e.g., tools or help to overcome barriers to care); and
- Poses low risk to Medicare/Medicaid because it is unlikely to:
 - Interfere with clinical decision making;
 - Increase costs to federal program or beneficiary; or
 - Raise patient care concerns.

(42 USC § 1320a-7a(i), definition of "remuneration"; 42 CFR § 1003.110, definition of "remuneration"; 81 FR 88393)

- Not cash or cash equivalents. (81 FR 88393)
- Not rewards or incentives for complying with treatment. (81 FR 88393-96)
- No similar AKS safe harbor, but risk is probably small if satisfy CMPL exception. (See, e.g., Adv. Op. 22-08)

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Free or Discounted Items or Services to Patients

OIG has providing following examples of “promoting access to care” exception:

Promotes access to care:

- Removes barriers to care, e.g.,
 - Free child care to attend program
 - Local transportation
 - Parking reimbursement
 - Self-monitoring tools
 - Maybe apps or fitness trackers
 - Education programs

(See, e.g., Adv. Op. 22-08 (provision of smart-phones for telehealth))

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Does NOT promote access to care:

- Rewards or incentives care, e.g.,
 - Movie tickets for compliance
 - Gift cards to reward compliance
 - Prize or reward for attending program

(81 FR 88393-97)

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Free or Discounted Items or Services to Patients

Certain participants in a **value-based enterprise (VBE)** may provide patient engagement tool or support to patient within VBE target population if:

- In-kind item, good or service, not cash or cash equivalent;
- Has direct connection to coordination and management of care;
- Recommended by licensed health professional;
- Advances one or more of certain specified goals;
- Not funded by specified prohibited entities;
- Aggregate retail value < \$500* annually;
- Not used to market other items or services;
- Make records available to HHS for 6 years.
- Not conditioned on type of insurance coverage for patient.

(42 CFR § 1001.952(hh))

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Free or Discounted Items or Services

May provide items or services for free or less than FMV if:

- **Retailer coupons, rebates or other rewards from a retailer** and;
 - Items or services offered or transferred on equal terms available to general public regardless of health insurance status; and
 - Offer or transfer not tied to provision of other Medicare/Medicaid services.

(42 CFR § 1003.110, definition of “remuneration”)

- No similar AKS safe harbor but probably small risk if comply with CMPL.

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Free or Discounted Items or Services to Patients

May generally offer free or discounted items to govt beneficiaries if:

- **Promotes delivery of preventative care, i.e.,**
 - Pre-natal or post-natal well-baby service or service listed in *Guide to Clinical Preventive Services* and payable by Medicare/Medicaid;
 - No cash or instruments convertible to cash; and
 - Value of incentive is not disproportionately large compared to the value of the preventative care service.

(42 USC § 1320a-7a(i), “remuneration”; 42 CFR § 1003.110, “remuneration”; see also 65 FR 24408; Adv. Op. 23-03)

- No similar AKS safe harbor, but risk is probably small if fit within the CMPL exception. (See, e.g., OIG Supplemental Compliance Program Guidance for Hospitals (1/05), 70 FR 4873).

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Free or Discounted Items or Services

Provider, physician or dialysis facility may provide **telehealth technologies to an individual with end-stage renal disease (ESRD)** who is receiving home dialysis payable by Part B if

- Telehealth technologies provided by currently treating provider.
- Not offered as part of advertisement or solicitation.
- Provided for purpose of furnishing telehealth services related to ESRD.

(42 CFR § 1001.110, definition of “remuneration”)

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Free Tests or Screening Exams

OIG has approved free screening services (e.g., free blood pressure check) where:

- Not conditioned on use of any items or services from any particular provider;
- Patient not directed to any particular provider;
- Patient not offered any special discounts on follow-up services; and
- If test shows abnormal results, visitor is advised to see his or her own health care professional.

(Adv. Op. 09-11, but note that Advisory Opinions are not binding on other parties)

- May use independent foundation but be careful.

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Free Transportation

May offer **free transportation** to govt beneficiaries under AKS safe harbor, 42 CFR 1001.952(bb):

Local Transportation

- Set forth in policy applied uniformly.
- Not determined based on volume or value of referrals.
- Not air, luxury, or ambulance-level transport.
- Not publicly marketed or advertised.
- Drivers not paid per beneficiary.
- Only for established patients within 25 miles or, in rural area, 75 miles.
- Costs not shifted to payors or individuals.

Shuttle on Set Schedule

- Not air, luxury, or ambulance-level transport.
- Not publicly marketed or advertised.
- Drivers not paid per beneficiary.
- Only within provider's local area, i.e., within 25 miles or, in rural area, 75 miles.
- Costs not shifted to payors or individuals.
- May also fit "promote access" CMPL exception
(42 CFR § 1003.110(i), "remuneration")

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Patient Incentives

- May pay **patient incentives under CMS-sponsored models** if:
 - Participant determines that incentive will advance goals of CMS-sponsored model;
 - Participant has direct connection to patient care unless otherwise specified by CMS;
 - Make available info to HHS upon request;
 - Furnished consistent with CMS model and satisfies CMS program requirements.

(42 CFR § 1001.952(ii)(2))

- ACO may make **incentive payment to assigned beneficiary under beneficiary incentive program** established under 42 USC § 1395jjj(m) for specified primary care services.

(42 CFR § 1001.952(kk))

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Waiving or Discounting Copays or Deductibles

May **waive or discount cost-sharing, copays, or deductibles** if:

- Good faith determination that (i) beneficiary is in financial need or (ii) unable to collect after reasonable collection efforts;
- Not offered as part of any advertisement or solicitation; and
- Not offered routinely.

(42 USC § 1320a-7a(i), "remuneration"; 42 CFR § 1003.110, "remuneration"; IC 41-348; *see also* Adv. Op. 12-16)

- Document factors such as local cost of living; patient's income, assets and expenses; patient's family size; scope and extent of bills; etc.
- Periodically review evaluation.

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Waiving or Discounting Copays or Deductibles

May waive or discount govt copays and deductibles if **satisfy AKS safe harbor**.

- Hospital inpatient stay paid under PPS, and
 - Waived amounts cannot be claimed as bad debt or shifted to any other payors;
 - Offered without regard to the reason for admission, length of stay, or DRG; and
 - Waiver may not be made as part of any agreement with third party payor with limited exceptions.
- FQHC or other health care facility under Public Health Services Grant.
- Pharmacy if certain conditions satisfied.
- Ambulance service if certain conditions satisfied.

(42 CFR § 1001.952(k))

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Certain Adjustments to Coinsurance and Deductible Amounts

- **Differentials in coinsurance and deductible amounts** as part of a benefit plan design if differential have been disclosed in writing to all beneficiaries, third party payers and providers to whom claims permitted.
- **Reduction in copay** amount for covered hospital outpatient services designated by HHS under 42 USC 1395l(t)(8)(B).
- **Waivers of Part D copays** on first fills of certain drugs if built into CMS-approved plan.
(42 CFR § 1003.110, “remuneration”)

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Writing Off Entire Bill

- Writing off entire bill for service is safer than waiving copays.
 - Payers usually don’t complain if not billed.
- Document legitimate purpose, *i.e.*, not intended to generate referrals, *e.g.*,
 - Unable to properly bill, *e.g.*, not medically necessary, substandard care, no documentation, failure to satisfy conditions for payment, *etc.*
 - Resolution of legitimate dispute or claim.
 - Financial need or unsuccessful attempts to collect.
 - Not inducement to order or receive other items or services.

(See 42 CFR § 1320a-7a(i); 42 CFR § 1003.110; OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)

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Writing Off Bills

OIG suggests that hospitals should:

- Have a reasonable set of financial guidelines based on objective criteria that document real financial need;
- Recheck patient's eligibility at reasonable intervals to ensure they still have financial need; and
- Document determination of financial need.

(OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)

- Other providers may want to adopt similar measures.

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Professional Courtesy

Beware professional courtesies to govt beneficiaries.

- No specific AKS or CMPL safe harbor.
- Consider whether intent is to induce referrals.
- Don't waive copays or deductibles or engage in "insurance only" billing.
- Consider whether other exceptions or safe harbors apply.

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Professional Courtesy

Professional courtesy to physicians, their family members, and/or perhaps their staff implicates Stark if the physician refers designated health services (DHS) payable by Medicare/Medicaid.

- Stark safe harbor requires:
 - Provider has formal medical staff.
 - Courtesy offered to all physicians on medical staff or in the service area regardless of referrals.
 - Services are of a type routinely provided by the entity.
 - Written policy approved in advance by governing body.
 - Not offered to govt patients unless good faith showing of financial need.

(42 CFR § 411.357(s); 72 FR 51064)

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Free or Discounted Items to Employees

If govt payers are involved:

- Offering **free or discounted services to your own employees** likely does not violate AKS, CMPL or EKRA if not tied to referrals.
 - Fits within bona fide employee safe harbor. (42 CFR § 1001.952(i); 42 USC § 220(b))
- But remember: offering free items or services to employees may implicate tax or employee benefit laws.
 - Benefits to employees are usually taxable.
 - May be structured to fit within employee benefit plan but ensure compliance with ERISA or similar laws.

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Prompt Pay Discounts

OIG has approved a **prompt pay discount** for govt beneficiaries if:

- Amount of discount reflects avoided collection costs, not an incentive to obtain services.
- Offered to all patients for all services without regard to patient's reason for admission, length of stay, or DRG.
- Not advertised so as to solicit business.
- Notified private payors of program.
- Costs not passed to Medicare, Medicaid or other payors.

(56 FR 35952; Adv. Op. 08-3)

- Remember: Advisory Opinions are not binding on third parties.

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Self-Pay Discount

- Medicare generally prohibits billing patients for covered services except for copays or deductibles.

But...

- HITECH Act and HIPAA prohibit provider from using or disclosing protected health info if the patient (or other person) pays for the episode of care and instructs provider not to submit to payor unless law requires disclosure.

(45 CFR § 164.522(a)(1)(vi))

- Exception to Medicare payment rule.
- Does not apply where state law requires the disclosure or submission to payer.

(78 FR 5628)

- Beware other laws...

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Self-Pay Discount

- Some states limit ability to charge different rates.
 - Charging insurers more than self-pay patients.
 - Charging self-pay patients more than insurers.
- Maybe facilities that submit cost reports. (See Provider Reimbursement Manual 15.1 at § 2203 (charge structure should be “applied uniformly”).)
 - Check with entity that prepares cost reports.
- FQHCs. (See MLN, *Federally Qualified Health Centers*, ICN 006397 (1/18) (“Patient charges must be uniform.”)).
- In some states, payor contracts may contain “most favored nation” clauses requiring providers to give their best rates.
 - Self-pay or other discounts may affect “usual and customary” charges.

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Self-Pay Discount

- OIG may exclude provider who charges Medicare “substantially in excess” of the provider’s usual charges.
(42 USC § 1320a-7(b)(6); 42 CFR § 1001.701(a)(1)).
 - Test: whether the provider charges more than half of its non-Medicare/Medicaid patients a rate that is lower than the rate it charges Medicare.
 - Presumably applies to specific charge or service.
- OIG has stated that it would not use the rule to exclude any provider or supplier that provides discounts or free services to uninsured or underinsured patients.

(See Adv. Op. 15-04; OIG Letter dated 4/26/00, available at <http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.html>)

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Paying Patient's Premiums

If paying Medicare Part B, C or D premiums:

- OIG approved payment of Part B premiums for ESRD patients where:
 - Patients are already receiving the services, so unlikely to induce services that might not otherwise be received.
 - No inappropriate patient steering to particular providers.
 - Patients are not coerced into enrolling in Part B.
 - Certain protections built in to protect Medicare program from additional costs.
 - OIG cautioned that it might reach different result in other circumstances.

(Adv. Op. 13-16; see also Adv. Op. 01-15 and Adv. Op. 13-16))

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Paying Patient's Premiums

If paying premiums for health insurance exchange:

- “HHS has significant concerns with this practice because it could skew the insurance risk pool and create an unlevel playing field in the Marketplaces. HHS discourages this practice and encourages issuers to reject such third-party payments. HHS intends to monitor this practice and to take appropriate action, if necessary.” (HHS Letter dated 11/4/13)
- Letter does not apply to:
 - Indian tribes and govt grant programs.
 - Payments made by private non-profit foundation based on defined criteria based on financial status that does not consider health status and payment covers entire year.

(HHS Letter dated 2/7/14; 79 FR 15240)

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Additional Resources

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<https://OIG.HHS.gov/compliance/>

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

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About OIG ▾ Reports ▾ Fraud ▾ **Compliance ▾** Exclusions ▾ Newsroom ▾ Careers ▾ COVID-19 Portal

Compliance

To help healthcare providers such as hospitals and physicians comply with relevant Federal health care laws and regulations, OIG creates compliance resources, which are often tailored to particular providers.

OIG's compliance documents include special fraud alerts, advisory bulletins, podcasts, videos, brochures, and papers providing guidance on compliance with Federal health care program standards. OIG also issues advisory opinions, which cover the application of the Federal anti-kickback statute and OIG's other fraud and abuse authorities to the requesting party's existing or proposed business

- Special fraud alerts, bulletins and other guidance.
- Advisory opinions.
- FR commentary accompanying AKS and CMPL rules.
- Compliance training videos.
- Enforcement actions.

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<https://oig.hhs.gov/compliance/advisory-opinions/>

The screenshot shows the top navigation bar of the OIG website, including the department logo, search bar, and 'Submit a Complaint' button. Below the navigation bar, there are dropdown menus for 'About OIG', 'Reports', 'Fraud', 'Compliance', 'Exclusions', 'Newsroom', 'Careers', and 'COVID-19 Portal'. The main content area features the heading 'Advisory Opinions' and a brief description: 'HHS-OIG issues advisory opinions about the application of certain fraud and abuse enforcement authorities to the requesting party's existing or proposed business arrangements.' To the right, under 'Additional Information', there are links for 'Advisory Opinion Process' and 'Frequently Asked Questions'. A 'View All Opinions' button is located below the description. At the bottom of the page, there is a search bar labeled 'Search opinions' and a 'Search' button.

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Resources

- OIG Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries* (8/02), <https://oig.hhs.gov/documents/special-advisory-bulletins/886/SABGiftsandInducements.pdf>.
- OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills* (2/04), <https://oig.hhs.gov/documents/other-guidance/908/FA021904hospitaldiscounts.pdf>.
- OIG Special Fraud Alert, *Routine Waiver of Copayments or Deductibles Under Medicare Part B* (12/94), <https://oig.hhs.gov/documents/physicians-resources/980/121994.pdf>.
- OIG Policy Statement, *Gifts of Nominal Value to Medicare and Medicaid Beneficiaries* (12/16), <https://oig.hhs.gov/documents/special-advisory-bulletins/887/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>.

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Resources

- [OIG Fact Sheet re Revisions to CMP Rules \(11/20\), https://oig.hhs.gov/documents/compliance/836/factsheet-rule-beneficiary-inducements.pdf](https://oig.hhs.gov/documents/compliance/836/factsheet-rule-beneficiary-inducements.pdf).
- [OIG Commentary to Final CMP Rule \(12/20\), 85 FR 77684.](#)
- [OIG Commentary to Final CMP Rule \(12/16\), 81 FR 88368.](#)
- [OIG Commentary to Final CMP Rule \(12/20\), 81 FR 88334.](#)
- [OIG Commentary to Final CMP Rule \(4/00\), 65 FR 24400.](#)

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<https://www.hollandhart.com/patient-inducements-gifts-discounts-waiving-co-pays-free-screening-exams-etc>

Holland & Hart People Capabilities Search by keyword

April 4, 2023

Patient Inducements: Gifts, Discounts, Waiving Co-Pays, Free Screening Exams, Etc.

By Kim Stanger

Although often well-intentioned, offering free or discounted items or services to patients (e.g., gifts, rewards, writing off copays, free screening exams, free supplies, etc.) may violate federal and state laws governing improper inducements, especially if the patient is a federal program beneficiary. The government is concerned that offering or rewarding such inducements to patients may result in overutilization, biased decisions concerning care, and increased costs to the Medicare, Medicaid or other government programs. Penalties for illegal inducements may include administrative, civil and criminal penalties; repayment to government programs; and exclusion from federal programs. Increasingly, private payors are also challenging such inducements. It is imperative that healthcare providers and their staff understand the applicable laws and limits.

I. Applicable Laws.

A. **Anti-Kickback Statute ("AKS").** The federal AKS prohibits anyone from knowingly and willfully soliciting, offering, receiving, or paying any form of remuneration to induce referrals for any items or services for which payment may be made by any federal healthcare program (e.g., Medicare, Medicaid, etc.) unless the transaction is structured to fit within a regulatory exception. (42 U.S.C. § 1320a-7b(b)). The statute has been interpreted to cover any arrangement where "one purpose" of the remuneration is to induce referrals for or receipt of federal program

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Questions?

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