

Applying the Rules





Free or Discounted Items or Services to Patients

For example:

- Marketing that offers free or discounted items.
- Free items or services, especially when tied to other services that are payable by govt payers.
- “Insurance only” billing.
- Writing off bills.
- “Refer a friend” rewards programs.
- “Thank you” gifts.
- Drawings, etc.

Free or Discounted Items to Patients



DANGER

Civil Monetary Penalties Law

Anti-Kickback Statute

Idaho Anti-Kickback Statute

Stark

IRS

Private Insurance Contracts



Freebies to Patients

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

- Remuneration is not likely to influence the beneficiary to order or receive items or services payable by federal or state health care program.
(42 USC 1320a-7a(5))
- 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))

Freebies to Patients

May offer free or discounted services to **govt beneficiaries** if:

- Financial need
 - Good faith determination that beneficiary has financial need or 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 CFR 1320a-7a(i); 42 CFR 1003.101; *see also* OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)

Freebies to Patients

- May offer free or discounted items to govt beneficiaries if:
 - Incentives to promote delivery of preventative care.
 - Payments meeting AKS safe harbor.
 - Any other remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs.
 - Retailer coupons, rebates or rewards offered to public.
 - Certain other situations.

(42 USC 1320a-7a(i); 42 CFR 1003.101)



Free Tests or Screening

- OIG has approved free screening services or tests (e.g., free blood pressure check by hospital) where:
 - **Not conditioned on the use of any items or services from any particular provider.**
 - **Patient not directed to any particular provider.**
 - **Patient not offered any special discounts or follow-up services.**
 - **If test shows abnormal results, visitor is advised to see his or her own health care professional.**

(Adv. Op. 09-11)

- *Advisory Opinions are not binding, but provide guidance.*

Free Transportation



- AKS safe harbor: 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, 50 miles
 - Costs not shifted to payers or individuals

(42 CFR 1001.952(bb))

Free Transportation

- **AKS safe harbor: shuttle service that operates 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, 50 miles**
 - **Costs not shifted to payers or individuals**

(42 CFR 1001.952(bb))

Waiving Copays or Deductibles



May waive or discount **govt** copays or deductibles if:

- Not offered as part of any advertisement or solicitation;
- Do not routinely waive copays or deductibles; and
- Waive or discount after
 - **good faith determination that the beneficiary is in financial need, or**
 - **unable to collect after reasonable collection efforts.**

(42 USC 1320a-7a(i)(6); 42 CFR 1003.101; *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.

Waiving Copays or Deductibles

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

- Hospital inpatient stay paid under PPS.
 - Waived amounts cannot be claimed as bad debt or shifted to any other payers.
 - Offered without regard to the reason for admission, length of stay, or DRG.
 - Waiver may not be made as part of any agreement with third party payer with limited exceptions.
- FQHC or other health care facility under any Public Health Services Grant.

(42 CFR 1001.952(k))

Writing Off Bills



- Writing off entire debt safer than waiving copays.
 - No one gets billed.
- The key: document legitimate purpose, i.e., not intent to generate referrals!
 - Resolution of legitimate dispute or settlement of claim.
 - Unsuccessful attempts to collect.
 - Financial need.
 - Other

Writing Off Bills

- Under CMPL, may waive or discount beneficiary's bills if:
 - Good faith determination that beneficiary has financial need or 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 CFR 1320a-7a(i); 42 CFR 1003.101; *see also* OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)

Writing Off Bills

- **OIG suggests that hospitals (and presumably other providers) should:**
 - **Have a reasonable set of financial guidelines based on objective criteria that documents real financial need.**
 - **Recheck patient's eligibility at reasonable intervals to ensure they still have financial need.**
 - **Document determination of financial need.**

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

Prompt Pay Discounts



- OIG has approved prompt pay discounts for **govt** beneficiaries if:
 - Amount of discount relates to avoided collection costs.
 - 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 payers of program.
 - Costs not passed to Medicare, Medicaid or other payers.

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

Prompt Pay Discounts

- Private payer issues
 - Idaho AKS prohibits regular practice of waiving deductibles.
 - Generally cannot discount copays and deductibles without violating managed care contracts unless payer agrees.
 - May adversely affect “usual and customary charges” and payer’s reimbursement under contract.
 - Payers may claim the benefit of the discount if the insurer pays within the relevant time.
- *Check your payer contract or contact your private payers.*

Self-Pay Discounts



- Providers may generally charge different patients or payers different amounts.
 - Negotiated rates for payers.
 - Negotiated rates or discounts for self-pay patients.
- Limitations:
 - Illegal discrimination (e.g., race, sex, religion, etc.).
 - Perhaps hospitals that submit cost reports.
 - In some states, payer 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.

Medicare “Substantially in Excess” Rule

- Provider may not charge 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.
- **OIG has stated that it would not use the rule to exclude or attempt to exclude any provider or supplier that provides discounts or free services to uninsured or underinsured patients.**

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



Paying Patient's Premiums

- If paying Medicare Part B, C or D premiums:
 - **OLG approved plan's 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.
 - **OLG 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))

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)

Paying Patient's Premiums

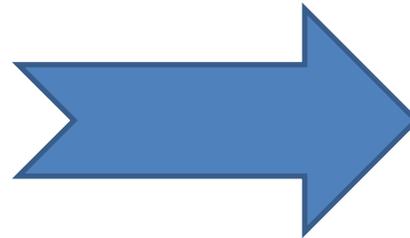
- If paying private insurance premiums (e.g., COBRA or other coverage):
 - Probably does not implicate AKS or CMPL unless it is tied to or induces referrals for services payable by govt programs.
 - May implicate Idaho AKS, but not tested.
 - COBRA regulations contemplate that COBRA premiums may be paid by third party.
 - Check payer contracts.
- *But stay tuned—this is a developing area of the law.*

Contracts with Referring Providers



Contracts with Referring Providers

- Employment
- Independent contractor or other services agreement
- Group compensation arrangement
- Lease for space or equipment
- Recruitment agreement
- Management or support services



**Stark
Anti-Kickback
Statute**

Contracts with Referring Providers

- Employees, especially physicians or their family members.
 - Identifiable services
 - Fair market value
 - Not based on the volume or value of referrals
 - Not based on referrals for ancillary services or services performed by others
 - May pay based on services the provider personally performs
 - Commercially reasonable

(42 CFR 411.357(d); 42 CFR 1001.952(i))

Contracts with Referring Providers

- Independent contractors or other services agreements.
 - Written agreement signed by parties.
 - Specifies services provided.
 - Terms remain in effect for at least one year.
 - Compensation:
 - Set in advance
 - Consistent with fair market value
 - Not based on volume or value of referrals.
 - May pay based on personally performed services.
 - May not pay based on referrals for ancillary services or services by others.
 - Commercially reasonable.

(42 CFR 411.357(c), (l); 42 CFR 1001.952(d))

Contracts with Referring Providers

- Group Practice compensation for physicians.
 - Distribution of overhead expenses and income based on formula set prospectively.
 - Compensation not based on volume or value of referrals for designated health services.
 - May pay based on personal productivity and “incident to” services, but not ancillary services or services performed by other employees that are not “incident to”.
 - May pay based on share of overall profits so long as subgroups have at least 5 physicians.
 - May pay based on other methods that do not reflect volume or value of designated health services.

(42 CFR 411.352(e), (g), (i))

Contracts with Referring Providers

- Leases for space and equipment
 - Written lease signed by the parties.
 - Specifies the premises covered.
 - Term is for at least one year; may not modify within 1 year term.
 - Space leased does not exceed that which is needed and is commercially reasonable.
 - Tenant has exclusive use of space or equipment.
 - Rent is set in advance, consistent with FMV, and not based on:
 - % of business generated in space or by equipment, or
 - Per-unit of service if includes services referred by landlord.

(42 CFR 411.357(a)-(b); 42 CFR 1001.952(b))

Ownership Interests

- Physician generally may not refer designated health services to an entity in which physician has ownership interest.
- Exceptions:
 - Group practice if satisfies definition of “group practice”.
 - Ownership interest in a hospital if certain conditions met.
 - Ownership of a rural provider, i.e., furnishes not less than 75% of DHS to residents of a rural area.

(42 CFR 411.355 and .356)

Gifts or Perks to Providers or Other Referral Sources



Gifts or Perks to Providers or Other Referral Sources

E.g., soliciting, giving or receiving:

- Gifts, e.g., “thank you” or appreciation gifts.
- Free items or services, e.g., meals, CME, travel, space, equipment, perks, insurance, etc.
- Discounted items or services, i.e., less than fair market value, professional courtesies, etc.
- Payments for services not performed.
- Payments for unnecessary services.
- Overpayments for items or services.
- Practice or expense subsidies.
- Business opportunities without investment.
- Failure to recoup money owed.

Free or Discounted Items to Referring Providers



DANGER

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Gifts or Perks to Providers

- Lower risk if entity receiving gift does not refer items or services payable by federal healthcare programs.
 - Stark, AKS and CMPL generally apply to referrals for items or services payable by govt programs.
- But no guarantee...
 - OIG has cautioned that carving out federal programs from specific transaction may not protect the parties if there are other referrals for federal programs between parties.
 - Still violates Idaho AKS and fee splitting statute.



Professional Courtesy

- Stark safe harbor applies if:
 - Practice has formal medical staff.
 - Written policy approved in advance.
 - Offered to all physicians in service area regardless of referrals.
 - Not offered to govt beneficiaries unless showing of financial need.
 - Does not violate AKS.

(42 CFR 411.357(s); 72 FR 51064)

- But beware AKS, Idaho AKS, and private payer contracts.

Professional Courtesy

- Especially beware waiving copays, deductibles or engaging in “insurance only” billing.
 - See prior discussion.
- 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 may be subject to ERISA or similar laws.

Gainsharing or Cost Saving Programs



- Hospital or CAH cannot knowingly make a payment, directly or indirectly, to a physician as an inducement to reduce or limit **medically necessary** services provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician.
 - Includes “gainsharing” programs.
- Physician cannot knowingly accept such a payment.
- Penalties:
 - \$2000 for each individual with respect to whom payment made.
 - Any other penalty allowed by law.

(42 USC 1320a-7a(b)(1); 42 CFR 1003.102)

Gainsharing Programs

- **OIG has periodically approved gainsharing in advisory opinions if certain safeguards included, e.g.,**
 - **Proposed plan does not adversely affect patient care.**
 - **Quality evaluated by third party.**
 - **Low risk that incentive will lead physicians to provide medically inappropriate care.**
 - **Payments limited in duration and amount.**
 - **Payments not tied to referrals or other suspect actions.**

(See, e.g., Adv. Op. 12-22)

- **OIG advisory opinions do not apply to Stark.**
 - **CMS proposed Stark exception, but was not finalized.**
- **CMS/OIG have issued interim rule waiving CMPL and Stark for ACOs.**