OIG Issues Special Advisory Bulletin on Gifts to Beneficiaries

By providing a “bright line rule” the OIG offers measurable guidance for beneficiary inducements.

On August 29, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services released a Special Advisory Bulletin (Bulletin) setting forth a “bright line rule” for the health care industry with respect to the statutory prohibition on the offering of gifts or other inducements to federal health care program beneficiaries. According to the Bulletin, unless a health care entity’s practices fit within one of five existing statutory exceptions or receives a favorable OIG Advisory Opinion specific to the entity, any gifts or free services to a beneficiary should not exceed the defined $10 per item or $50 annually per patient limits.

The OIG also indicated that any Advisory Opinions or additional exceptions to the prohibition on inducements would be “few in number and narrow in scope,” though it is considering seeking public comment on two additional regulatory exceptions related to complimentary local transportation and free goods/services in connection with government-sponsored clinical trials. Finally, valuable services or remuneration furnished to financially needy beneficiaries by an independent entity, but funded by providers, remains permissible, provided that the independent entity determines need and patient choice of provider is preserved.

Impact on Health Care Entities

Because the OIG has stated that the Bulletin provides a “bright line rule” for practices regarding beneficiary inducements, health care entities should take care to comply with its terms. Health care entities should review both their active and passive practices related to beneficiaries to ensure that any gifts to beneficiaries are of nominal value or otherwise meet an exception to the prohibition on inducements. As the OIG states in the Bulletin, for practices that do not clearly meet the “bright line rule,” health care entities should consider seeking an OIG Advisory Opinion. Health care entities should consult counsel to review their practices and assist in seeking Advisory Opinions, where appropriate, in order to avoid sanctions under applicable law.

Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), with certain defined exceptions, provides that a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration 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 civil money penalties of up to $10,000 per wrongful act. The OIG enforces this law administratively.
The law is designed to reduce overutilization and promote patient choice based on need and quality of care. Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider can lead to overutilization and undermine patient choice based on need, cost and quality of care. It can also give providers an economic incentive to offset the costs of the gift by providing unnecessary services or by substituting cheaper or lower quality services. The use of free gifts also favors large providers with greater financial resources over small providers.

**Bright Line Rule**

As such, the OIG released this Bulletin as a “bright line rule” for providers to use to determine if their practices comply with the prohibition on gifts to beneficiaries. The OIG defines the “bright line rule” using four principles:

1. **Nominal Value:** The OIG interprets the gift prohibition to permit providers to offer Medicare or Medicaid beneficiaries inexpensive gifts (other than cash or cash equivalents) or services. “Inexpensive” is defined by the OIG as a retail value of no more than $10 individually and no more than $50 in the aggregate annually per patient, subject to adjustments for inflation at the OIG’s discretion.

2. **Statutory Exceptions:** More expensive items or services may be provided only if they fit one of five statutory exceptions:
   - waivers of cost-sharing amounts based on financial need;
   - properly disclosed copayment/deductible differentials in health plans;
   - incentives to promote the delivery of certain preventive care services;
   - any practice permitted under the federal anti-kickback statute (42 CFR 1001.952); and
   - waivers of hospital outpatient copayments in excess of the minimum copayment amounts.

3. **New Exceptions:** The OIG is considering limited additional regulatory exceptions for complimentary local transportation and for free goods in connection with participation in certain government-sponsored clinical studies.

4. **Limited Advisory Opinions:** While the OIG will continue to review requests for Advisory Opinions, due to perceived difficulty in creating principled standards for categories of beneficiaries or types of inducements, the OIG will likely limit favorable opinions to situations closely analogous to the law’s existing exceptions.

**Specific Guidance**

The OIG also offered specific guidance on each aspect of the prohibition on inducements to beneficiaries as follows:

**Remuneration**

The OIG broadly defines “remuneration” as “anything of value,” noting that implicitly almost every good or service has a monetary value. Importantly, based on Congressional intent, the OIG has excluded from the prohibition “inexpensive gifts of nominal value.” The OIG defines “inexpensive” as having retail value of no more than $10 per item or $50 in the aggregate per patient on an annual basis.

The OIG also clarified three of the statutory exceptions to the prohibition:

- **Waivers of cost-sharing amounts** are excepted if they are non-routine, unadvertised, and based on individualized determinations of financial need or exhaustion of reasonable collection efforts. Paying the premium for a beneficiary’s Medicare Part B or supplemental insurance is not protected by this exception.

- **Properly disclosed copayment or deductible differentials in health plans** are excepted for incentives that are part of the health plan design (e.g., lower plan copayments for preferred providers, mail order pharmacies or generic drugs), but not for waivers of Medicare or Medicaid copayments, which may be covered by a separate exception (see above).

- **Incentives to promote the delivery of preventive care** are excepted for defined preventive care items and services, but may not be in the form of cash or cash equivalents or be disproportionate to the value of the care provided. Preventive care is defined as care that is covered by Medicare or Medicaid and is either...
pre-natal or post-natal well-baby services or services described in the *Guide to Clinical Preventive Services.*

**Inducement**

The prohibition on inducements precludes the offering of remuneration where the offeror knows or should know that the remuneration is likely to influence the beneficiary to order or receive items or services from a particular provider. According to the OIG, inducement may occur by active or passive offers of valuable goods or services (e.g., even “word of mouth” promotions are suspect), and by the provision of “freebies” to existing customers who have continuing relationships with the provider.

**Beneficiaries**

Due to a lack of statutory authority, the OIG also refused to find exceptions to the prohibition based on beneficiary status, such as chronic illness or financial need. First, the OIG believes that although specialty providers who offer complimentary items or services to chronic disease sufferers provide a therapeutic benefit to patients, at the same time they are targeting a population more likely to generate business for the provider. In addition, because Congress included the Medicaid program (covering the financially needy) within the prohibition and provided a narrow exception for non-routine waivers based on financial need, the OIG determined that Congress had no intent to completely exempt gifts to financially needy beneficiaries. As such, the OIG cannot recognize exceptions based on particular characteristics of beneficiaries.

**Provider, Practitioner, Supplier**

The prohibition on inducements applies to most providers, practitioners and suppliers, except for entities the OIG has excluded such as:

- Health plans that offer incentives to Medicare and Medicaid beneficiaries to enroll in a plan.
- Drug manufacturers, unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefit management companies or other entities that file claims for payment under federal health care programs.

**New Exceptions**

Under regulatory authority to create new exceptions, the OIG may issue regulations or Advisory Opinions interpreting the prohibition on inducements. According to the Bulletin, such exceptions will be “few in number and narrow in scope” because:

- Exceptions will cause providers to compete for business by offering more and more valuable items and services to beneficiaries, creating exactly the activity that the statute prohibits.
- Because almost all goods and services have monetary value, no meaningful basis exists to distinguish between the remuneration offered or the recipient beneficiaries, resulting in arbitrary application of the law.

Nonetheless, the OIG indicated it might propose two new safe harbors for:

- **Complimentary local transportation**—This potential exception would be limited to beneficiaries who reside in the provider’s primary service area and may involve services of greater than nominal value, but would not cover luxury or specialized transportation like limousines or ambulances. Transportation to providers other than the donor of the transportation may also be permitted, subject to anti-kickback analysis of the benefit conferred by the donor on the other provider.
- **Government-sponsored clinical trials**—This exception would cover “freebies” offered in connection with HHS-sponsored clinical trials.

Finally, the OIG:

- is currently reviewing a proposal to permit certain dialysis providers to purchase Medicare supplemental insurance for financially needy persons in accord with the principles set forth in the Bulletin.
- is actively encouraging providers to seek Advisory Opinions related to unadvertised waivers of copayments and deductibles.
• will permit, as in previous Advisory Opinions, independent entities such as patient advocacy groups to provide free or other valuable services or remuneration to financially needy beneficiaries, even if funded by providers, provided that the independent entity makes an independent determination of the financial need and the beneficiary’s receipt of the remuneration does not depend directly or indirectly on the beneficiary’s use of any particular provider.12

Conclusion
By providing a “bright line rule” the OIG offers measurable guidance for beneficiary inducements. Unless a favorable OIG Advisory Opinion is obtained, those that exceed the $10 per item/$50 annual aggregate per patient standards or that do not meet statutory exceptions are not permissible. Health care entities should review their beneficiary and promotional practices to ensure that they are in compliance with the limits of the prohibition on gifts to beneficiaries, and obtain advise of counsel with respect to seeking Advisory Opinions.

Endnotes

2 Id.

3 See Social Security Act Section 1128(A)(a)(5).

4 Safe harbors exist under the federal Anti-kickback Statute for such things as warranties, discounts, employee compensation, waivers of certain coinsurance and deductible amounts, and increased covered, reduced cost-sharing amounts or reduced premium amounts offered by health plans. See 42 CFR 1001.952.

5 See Social Security Act Section 1128(A)(a)(5).

6 The OIG does note that some services, such as companionship services by volunteers, have psychological rather than monetary value.


9 The “should know” standard includes deliberate ignorance or reckless disregard; no proof of specific intent is required. See 42 CFR 1003.101.

10 Incentives to influence an enrollee to select a particular provider, practitioner or supplier within the health plan are prohibited, unless a copayment differential that is part of a health plan design.

11 See Social Security Act Section 1128(A)(a)(5).

12 The OIG cites as an example the American Kidney Fund’s program to assist needy patients with end stage renal disease with funds donated by dialysis providers, as discussed in OIG Advisory Opinion Nos. 97-1 and 02-1.