



Kim Stanger

Partner
208.383.3913
Boise
kcstanger@hollandhart.com

Offering Free Screening Tests to Patients

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Healthcare providers often offer free screening tests or services as a way to generate business for their facility or practice; however, doing so may violate federal and state laws unless structured properly. The federal Anti-Kickback Statute (“AKS”)¹ and Civil Monetary Penalties Law (“CMPL”)² generally prohibit offering free or discounted items or services to patients as a way to generate business payable by Medicare, Medicaid or other federal healthcare programs unless the arrangement fits within a regulatory exception.³ Violations of the AKS or CMPL may result in criminal, civil, and/or administrative penalties.

Free screening programs may be allowed under the following circumstances:

- 1. Items of Nominal Value.** The Office of Inspector General (“OIG”) has approved gifts of nominal value to patients, which the OIG interprets as \$15 per gift and aggregate of \$75 per patient per year. Although the OIG’s analysis is limited to the CMPL, the OIG would probably apply the same limits to the AKS; accordingly, if the free screening has a value of less than \$15, there is likely little risk.
- 2. Items that Promote Access to Care and Create Minimal Risk of Abuse.** The CMPL contains a broad and somewhat ill-defined exception for:
 - items or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by (i) being unlikely to interfere with, or skew, clinical decision making; (ii) being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) not raising patient safety or quality-of-care concerns.

(42 CFR § 1003.103, definition of “remuneration”).
- 3. Financial Need.** The CMPL allows providing free or discounted items to those in financial need if:
 - (i) The items or services are not offered as part of any advertisement or solicitation; (ii) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a State health care

program (...); (iii) there is a reasonable connection between the items or services and the medical care of the individual; and (iv) the person provides the items or services after determining in good faith that the individual is in financial need.

(42 CFR § 1003.103, definition of “remuneration”).

4. **Certain Preventative Services.** The CMPL contains an exception for certain preventative care services, including some prenatal services, a post-natal well-baby visit, or specific clinical services described in the current U.S. Preventive Services Task Force's Guide to Clinical Preventive Services, provided that such services are not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. (42 CFR § 1003.103, definition of “remuneration” and “preventative services”).
5. **Services Not Tied to Federal Program Business.** Even if the screening program does not fit within one of the foregoing exceptions, providers may still offer free screening programs so long as there is no improper intent to induce referrals and there is minimal risk of Medicare or Medicaid program abuse. In Advisory Opinion 09-11, the OIG approved a hospital's free blood pressure screening program where (i) the free screening was not conditioned on the use of any other goods or services from the hospital; (ii) the patient receiving the screening was not directed to any particular provider; (iii) the hospital did not offer the patient any special discounts on follow-up services; and (iv) if the screening was abnormal, the patient was advised to see their own health care professional. Under these circumstances, the OIG concluded that the test was not improperly tied to the provision of other services by the hospital. Although advisory opinions are only binding on the parties to the opinion, providers likely face minimal risk if they incorporated similar safeguards in their screening programs. Conversely, they face AKS and CMPL penalties if they use the program as a way to generate and/or steer Medicare and Medicaid beneficiaries to their own facility or program.

State Laws. States may have their own versions of the AKS, CMPL, or similar laws; accordingly, providers must also check their own state laws when establishing free screening programs or offering free services.

¹42 USC 1320a-7b(b).

²42 USC 1320a-7a.

³See OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (August 2002), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

Holland & Hart, 800 W Main Street, Suite 1750, Boise, ID 83702
email: kcstanger@hollandhart.com, phone: 208-383-3913

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