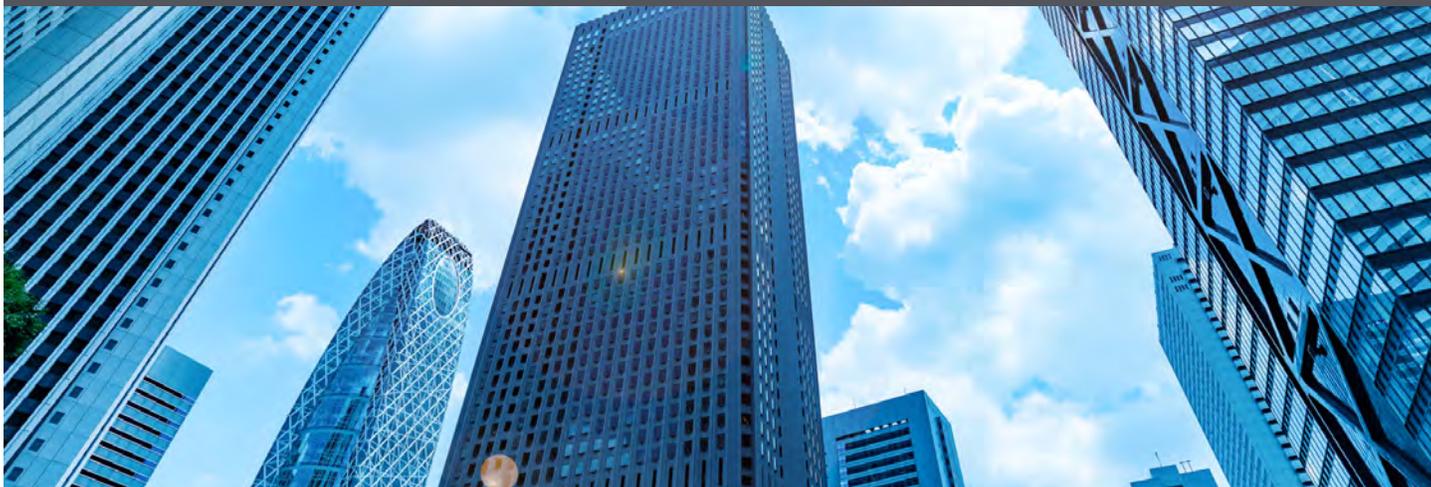


White Collar Defense & Investigations



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Best Practices for Healthcare Providers Offering Free Services to Patients under Federal Anti-Kickback Laws

The federal government is increasingly levying enforcement actions against all types of healthcare providers. These enforcement actions can result in civil and/or criminal liability for violations of the False Claims Act, Civil Monetary Penalties Law, Stark Law, and/or the Anti-Kickback Statute, resulting in monetary fines, suspension or exclusion from federal healthcare programs, and even imprisonment. Healthcare providers should, therefore, focus on designing detailed compliance programs that comply with the Sentencing Guidelines, starting with a close review of the official guidance materials issued by the Office of the Inspector General (“OIG”) for healthcare providers. Because the occasional provision of certain free medical services—such as preventive care screenings—can lead to enforcement actions as they can be viewed as illegal payments made to encourage future business and referrals, healthcare providers who provide such services should also consider the following analysis and recommendations.

The federal Anti-Kickback Statute (the “AKS”) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal healthcare program.¹ “Remuneration” can include the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

Similarly, Section 1128A(a)(5) of the Social Security Act (the “CMP”) imposes civil monetary penalties against any person who gives something of value to a Medicare or state healthcare program (including 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 any item or service for which payment may be made, in whole or in part, by Medicare or a state healthcare program.² Again, “remuneration” under the CMP includes “transfers of items or services for free or for other than fair market value.”³

A healthcare provider can violate the AKS or CMP by providing free services, including preventive care exams or disease screening, to induce referrals for items or services reimbursable by a federal healthcare program, or by knowing (or having reason to suspect) that giving free services to state healthcare program beneficiaries would likely influence their choices regarding providers who supply items or services payable through a state healthcare program. However, certain exceptions exist. For example, the CMP excludes from the definition of “remuneration” the provision of incentives aimed at promoting the delivery of preventive care, where delivery of the preventative care is not tied to the provision of other services reimbursed by Medicare or an applicable state healthcare program.⁴

Many advisory opinions released by the OIG have addressed the provision of free preventive care or disease screening services, providing helpful recommendations and guidelines for providers.⁵ Healthcare providers offering free screening or preventive care services to patients should consider the following guidance:

1. Avoid recommending that patients return for any future services or follow-up appointments (whether free or not) as a result of their decision to take advantage of the free service. Instead, advise patients to consult their primary care physicians for further questions or medical information they may seek. This will help dispel any suspicion that free services are being provided to recruit business or referrals, which could constitute unlawful remuneration.
2. Consider directly advising patients—whether verbally or in writing, possibly via a written patient acknowledgement form—that you are not, by providing the free service, promoting any certain medical provider, item, or service.
3. Do not promote other for-cost office services in connection with the free service offered.
4. Do not collect information about patients' insurers or need for federally reimbursable services in the process of administering free services.
5. Do not bill any healthcare program for free services or otherwise increase costs to healthcare programs in connection with the free services.
6. Provide free services only within your own office as opposed to at outside locations or events.
7. Limit the advertising of any free services provided. This includes the following:
 - a. Do not encourage other medical professionals to send patients to your office specifically for free services.
 - b. Avoid including any messaging specifically promoting free services on promotional materials (such as flyers and mailings) distributed at nearby pharmacies, unaffiliated medical offices and facilities, etc.
 - c. Do not indicate that a free service is worth substantial value. For example, a free service should not be directly advertised (whether by word of mouth, visual signage, educational materials, or otherwise), or actively discussed by office staff, as being substantially valuable, previously recommended by medical professionals, or performed by trained and licensed professionals.
 - d. When appropriate and necessary, frame the provision of free services as a vehicle for promoting wide, community-based initiatives. For example, an office providing free blood pressure readings should position the service as part of a larger effort to raise awareness for diabetes or heart disease.

Regardless of whether providers view free preventative care screening services as a norm in certain healthcare practices, such services can lead to enforcement actions if viewed as being made to encourage future business and referrals. Providers should, therefore, consider these guidelines when offering free services to patients and should develop internal compliance programs that account for these guidelines in an effort to avoid federal enforcement actions, as well as qui tam or whistleblower claims, related to the provision of free services.

For additional information, please contact:

Nicholas C. Harbist
609.750.2991 | harbist@blankrome.com

Lauren E. O'Donnell
215.569.5735 | odonnell@blankrome.com

Michaela L. Cronin
215.569.5611 | mcronin@blankrome.com

1. See 42 U.S.C. § 1320a-7b.

2. See 42 U.S.C. § 1320a-7a.

3. *Id.* at § (i)(6).

4. See *id.* at subpart (D). "Preventive care" includes any service that both: (1) "is a prenatal service or a post-natal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force's Guide to Clinical Preventive Services," and (2) "is reimbursable in whole or in part by Medicare or an applicable State health care program." 42 C.F.R. § 1003.110.

5. The recommendations made herein are based on Advisory Opinion Nos. 09-11, 00-3, 13-13, 12-17, 10-08, 11-04, 03-7, 06-01, and 18-05, which are available on the OIG's website at oig.hhs.gov/compliance/advisory-opinions/index.asp. These materials are released only for advisory purposes and do not constitute binding law.