

Key Regulations Impacting Healthcare Marketing:

ENTERTAINMENT AND GIFTS

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Marketing is an integral component of any business enterprise's efforts to sustain and expand its economic base. In the healthcare industry, however, common marketing practices that are truly effective and legal in almost every other industry are strictly prohibited. While the healthcare regulatory framework is extensive and highly complex, this article focuses on some of the principal Federal statutory bases that govern imaging providers' marketing endeavors, including the Federal Stark Law ("Stark")¹, and the Medicare and Medicaid Anti-kickback Statute (the "AKS")². This article is intended to provide only a brief summary of the Stark and AKS regulatory framework governing specific healthcare marketing activities, including providing entertainment and/or gifts to referral sources. It does not address every regulatory aspect of healthcare marketing, thus, providers engaging in specific marketing activities should have their programs reviewed to ensure compliance with applicable law.

Healthcare marketing and the AKS

The AKS is an intent-based statute, which contains both civil and criminal penalties. Any arrangement, including many marketing activities, in which anything of value changes hands between a referral source and a third party in connection with the provision of services paid for by a federal program potentially implicates the AKS. Due to the breadth of the potential application of the criminal law, the Office of the Inspector General ("OIG") was required to develop "safe harbor" regulations designed to protect various payment and business practices. Protection of a practice under a safe harbor avoids treatment as a criminal offense under the law. If an arrangement falls outside the safe harbor it is not per se illegal but the facts and circumstances behind the arrangement must be carefully reviewed.

At its core, marketing is generally designed to increase business through different incentives. Thus, by their very nature, many common marketing activities will implicate the AKS. Importantly, imaging providers must keep in mind the AKS is very broadly worded and applies to many marketing activities that target both patients and physicians (or other referral sources). The OIG has also issued several advisory opinions addressing marketing activities³.

The following summarizes some key concepts that imaging providers should keep in mind when designing and

implementing marketing programs that will be able to withstand regulatory scrutiny:

Entertainment and gifts

In the healthcare marketing industry, it has been a common practice for providers to entertain and present gifts (and other services and items of value) to physicians and other potential referral sources. Imaging providers must be aware these types of activities do fall squarely within the ambit of the AKS. Specifically, the OIG⁴ has issued compliance guidance that directly addresses this area, suggesting gifts, gratuities, and other entertainment activities raise risk when they involve parties in a position to refer services or influence referrals to the provider. As a result, before engaging in these types of activities, providers should adhere to certain procedural safeguards designed to minimize AKS risk. Below are some examples of procedural safeguards and policy concepts that should be implemented by imaging providers when engaging in marketing activities that involve providing gifts to and/or entertaining referral (or potential referral) sources:

- The imaging provider's – the IP – administration should be notified of all marketing activities with referring physicians (as well as other referral sources). This will allow the IP to coordinate, monitor, track, and evaluate such activities from a compliance perspective.
- The IP should never provide referral sources with cash gifts. Any non-monetary gifts can never be tied to referrals, should be nominal in value, and tied to educational/business sessions.
- In the event a referring physician or other referral source suggests or represents that referrals or continued referrals is conditioned upon the IP providing entertainment or gifts to such individual, the IP should immediately refrain from any marketing effort with that individual. Similarly, the IP must avoid making any statements to a referral source that could be construed to mean either (a) increased referrals will translate into more lavish entertainment, or (b) conversely, any decrease in referrals will result in a reduction of entertainment.
- The IP must not correlate its marketing expenditures to the volume or value of referrals to the IP by the referral source.

- When entertainment takes the form of dining, the IP should spend a significant portion of time discussing business/education matters with the individual.
- The IP must be mindful of the amount expended on entertainment, both in terms of any specific episode (e.g., dinner), and the aggregate expenditure on any single referral source during a year. Simply put, as the amount expended increases, the likelihood of being able to view the entertainment as an inducement to refer increases.

The foregoing principles should be documented by the imaging provider and should be observed when the provider coordinates any type of marketing event.

Marketing representatives

To successfully implement certain marketing efforts, a growing number of imaging providers are engaging marketing representatives (often referred to as “Physician Liaisons”) to visit physician offices with the goal of building relationships with the physicians and their staffs. Imaging providers should be mindful their financial relationships (e.g., independent contract or employment) with these Physician Liaisons fall within the ambit of the AKS. Accordingly, these relationships should be structured in light of the applicable AKS safe harbors. With respect to Physician Liaisons that are independently contracted with an imaging provider, the agreement should be structured in light of the personal services and management contracts safe harbor⁵. Among other requirements, this safe harbor mandates that the aggregate compensation paid to the Physician Liaison be set in advance, consistent with fair market value in an arm’s length transaction and not determined in a manner that takes into account any referrals. As a practical matter, this will preclude the Physician Liaison from receiving compensation based upon a percentage commission mechanism. If the imaging provider employs (rather than independently contracts with) the Physician Liaison, the AKS provides more flexibility, as the employee safe harbor⁶ allows the employer to pay an employee any amount (including percentage-based compensation) for their employment services. The key is the imaging provider can only take advantage of this safe harbor if the employee is truly a bona fide employee as determined by the Internal Revenue Service.

Healthcare marketing and Stark

Stark is a broad prohibition that bans physician referrals of Medicare beneficiaries to entities with which they, or members of their immediate family, have a financial relationship for certain services itemized in the statute, referred to as “designated health services” (“DHS”)⁷. DHS include, among others, inpatient and outpatient hospital services, and radiology and certain other imaging services. Stark is a strict liability statute, which means that intent is not required. For purposes of Stark, a financial relationship may arise from a compensation arrangement, which includes the provision of anything of value to a referring physician. As a result, imaging providers that engage in marketing activities that target physicians or physician owned entities, including, providing entertainment or gifts to such physicians and/or entities, must be aware that such

marketing activities directly implicate Stark. If Stark is implicated, and an exception is not met, a provider will be subject to severe sanctions, including denial of filing claims for those referred services.

Under Stark, there is an exception for “non-monetary” compensation⁸ that applies to certain marketing activities. Under this exception, imaging providers that furnish something of value (e.g., meals, entertainment, non-cash gifts such as tickets, etc.) to a referring physician up to an annual limit of \$300⁹ will be protected by this exception. Notably, if an imaging provider’s marketing activities do not comply with this exception, it will not be able to lawfully bill for any DHS (e.g., imaging services) ordered by that referring physician.

As noted above, imaging providers should implement certain procedural safeguards when engaging in marketing activities that involve providing gifts to and/or entertaining physician referral sources. This should include tracking and maintaining documentation regarding aggregate expenditures by the provider for every referring physician to ensure the aggregate annual expenditure limitation is not exceeded. In the event an imaging provider accidentally exceeds the limit (not to exceed 50 percent), the Stark law provides the excess can be corrected by repayment of the excess by the referring physician within the earlier to occur at the end of the calendar year or 180 days.

Concluding remarks

Given the complex healthcare regulatory framework, imaging providers need to ensure they adhere to certain procedural safeguards when engaging in marketing activities with physicians or other entities or individuals who refer, or are in a position to refer, business. In practice, this should cover any and all activities involving, for example, entertainment activities with referral sources, and the provision of any gifts to referral sources.)))

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FOOTNOTES

- 1 42 U.S.C. Section 1395nn et. seq.
- 2 42 U.S.C. Section 1320a-7b.
- 3 See, for example OIG Advisory Opinions 99-12, 04-03, 06-17, and 06-20 all of which can be accessed at www.oig.hhs.gov.
- 4 See, the “OIG Compliance Program Guidance for Pharmaceutical Manufacturers” at 68 Fed. Reg. 23731 (2003). Please note that although this guidance was issued for the pharmaceutical industry, the underlying concepts and principles set forth in the guidance apply to other sectors of the healthcare industry, including imaging providers. It is also important to note that, in addition to the AKS, an imaging provider (unlike pharmaceutical manufacturers) that engages in certain marketing activities which target physicians must also ensure that the activities are structured to comply with the Federal Stark law. This will be discussed later in this article. Further, in addition to the OIG Guidance, private sector industry guidance has also been issued which should be reviewed when structuring marketing programs. See for example, the PhRMA Code on Interactions with Healthcare Professionals, and the AdvaMed Code of Ethics on Interactions with Healthcare Professionals.
- 5 42 C.F.R. Section 1001.952 (d).
- 6 42 C.F.R. Section 1001.952 (i).
- 7 42 U.S.C. Section 1395nn.
- 8 42 C.F.R. Section 411.357(k).
- 9 This amount is adjusted annually for inflation and is reported as \$355 for 2009.