Regulatory Review: Healthcare Marketing—Navigating the Regulatory Landscape

By Adrienne Dresevic, Esq. and Carey F. Kalmowitz, Esq., The Health Law Partners, PC

This article is the first in a new Link *column called "Regulatory Review."*

Marketing is an integral component of any business enterprise's efforts to maintain and expand its economic base. At the beginning of this New Year, many imaging providers (IPs) likely will strategize about their 2010 marketing programs as they contemplate the prospects of declining reimbursement and heightened regulatory scrutiny. As IP managers develop their plans, they must be mindful that marketing practices which are commonly applied in most other industries potentially might implicate significant compliance risks for healthcare providers. While the healthcare regulatory framework is extensive and highly complex, this month's column will focus solely on the principal federal laws that govern IPs' marketing practices with referrals sources, in particular, the Medicare and Medicaid Anti-kickback Statute (AKS), and the Federal Stark Law ("Stark").

Healthcare Marketing and the AKS

The AKS is an intent based statute which contains both civil and criminal penalties. Any arrangement in which anything of value is exchanged 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. Since marketing inherently is designed to cultivate business (including imaging services reimbursed by federal programs) through the offering of incentives, many common marketing activities potentially violate the AKS. Thus, together with evaluating the efficacy of a particular marketing activity, IPs should design their marketing with a view towards mitigating the attendant compliance risks.

Healthcare providers customarily entertain and offer gifts and other items, (eg, event tickets, etc) to physicians and other persons in a position to refer or arrange for referrals. In a progressively more competitive environment, the pressure to enhance imaging revenue often leads IPs to expand their networks of referral sources, and marketing often is viewed as the means to do so. As discussed in compliance guidance issued by the Office of Inspector General, gifts, gratuities, and other entertainment activities trigger potential AKS risks when they involve parties in a position to refer services or influence referrals to the provider. As a result, providers should implement certain safeguards designed to reduce these risks. Below are certain procedural safeguards that IPs should consider when structuring their marketing programs:

- The IP's administration should be notified of all marketing activities with referring physicians (and other referral sources). This will permit 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 that 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. Also, the IP must avoid making any statements to a referral source that could be construed to mean either (a) that increased referrals will translate into more lavish entertainment, or (b) conversely, that 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 aware of the amount expended on entertainment, both in terms of any specific episode (eg, dinner), and the aggregate expenditure on any single referral source during a year. Simply put, the likelihood of the arrangement being viewed as an inducement to refer increases in proportion to the level of entertainment expenditures.

Healthcare Marketing and Stark

Stark is a broad prohibition that bans physician referrals of

. . . continued on next page

Regulatory Review: Healthcare Marketing—Navigating the Regulatory Landscape

. . . from previous page

Medicare beneficiaries to entities with which they (or immediate family members) have a financial relationship for "designated health services" (DHS), which include, among others, radiology and other imaging services, unless an exception applies. For Stark purposes, a financial relationship may arise from a compensation arrangement, which includes the provision of anything of value to a referring physician. As a result, IPs which market to physicians or physician owned entities should be cognizant that such activities directly implicate Stark. If Stark is triggered, and an exception is not met, a provider will be subject to severe sanctions, including denial of claims for those referred services.

Stark contains an exception for "non-monetary" compensation that applies to certain marketing activities. Under this exception, IPs that furnish something of value (eg, meals, entertainment, non-cash gifts such as event tickets, etc) to a referring physician up to an annual limit of $355 will be protected by this exception. Notably, if an IP's marketing activities do not comply with this exception, it will not be able to lawfully bill for any imaging services ordered by that referring physician.

As noted above, IPs should implement certain procedural safeguards when engaging in marketing activities that involve providing gifts to, and/or entertaining, physician referral sources. These should include, in particular, those principles discussed above. In the event that an IP inadvertently exceeds the limit (not to exceed 50%), Stark provides that the excess can be corrected by the referring physician repaying such excess by the end of the calendar year or 180 days from the date of such payment, whichever is first.

Conclusion

Given the complex healthcare regulatory framework, IPs need to ensure that they adhere to certain procedural safeguards when engaging in marketing activities with referral sources. In practice, this should cover any and all activities, involving, for example, entertainment activities and the offering of any gifts to referral sources. While IPs realistically cannot forego marketing, by implementing the practices discussed above, they can meaningfully reduce the AKS and Stark risks associated with marketing.