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Losing sleep over health care marketing arrangements

By Lawrence Conn

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As with any industry, health care providers typically find marketing a valuable means of ensuring economic vitality, goodwill, and community outreach. Unlike almost any other industry, however, health care providers are faced with substantial limitations and potential criminal liability in connection with these efforts, even when no false or misleading claims are made and no coercive tactics are used. The principle hurdle providers face is the federal Anti-kickback Statute [42 U.S.C. § 1320-7b(b)], which prohibits remuneration not only for referrals, but also in exchange for, or to induce recommending an item or service covered by a governmental health care program. Many states have laws that equal or even exceed the scope of the federal Anti-kickback Statute, often extending to items or services regardless of the payer. Because recommending use of items and services is the very essence of marketing, health care providers operate in a highly unusual and potentially perilous legal environment.

The Department of Health & Human Services, Office of Inspector General (OIG) has expressed a longstanding concern regarding health care marketing. Back in 1991, when the initial Anti-kickback Statute safe harbors (i.e., regulatory exceptions) were finalized, the OIG declined to offer any special protections for marketing, stating: [W]e believe that many marketing and advertising activities may involve at least technical violations of the statute.[1]

These concerns have continued to play out through a long series of OIG Advisory Opinions, including two recent opinions addressing marketing arrangements for sleep testing laboratories, which are addressed later in this article.

Safe harbor

Although the OIG declined to offer any special protection for marketing arrangements, it also noted that marketing and advertising can potentially fit within the personal services and management contracts safe harbor to the Anti-Kickback statute.[2] However, unless a provider engages or employs an exclusive, full-time marketer, whom it pays on a wholly fixed-fee basis, it will be difficult to meet this safe harbor. Among other standards, the safe harbor requires that any part-time arrangement must specify "exactly the schedule of such intervals, their precise length, and the exact charge for such intervals."[3] It may be highly impractical for the parties to specify in advance the exact periods during which a marketer will perform its services, particularly if the marketer is a consultant or other independent contractor, rather an employee of the provider. Moreover, unless the marketer is paid on a fixed hourly basis and the marketing services are performed in discrete time chunks, it would likely be impossible to specify the "exact charge" for each interval of service rendered.

Failure to meet a safe harbor does not mean an arrangement violates the Anti-kickback Statute, but rather that it will be subject to scrutiny under the statute and potentially could be found to be a violation. Still, marketing arrangements that fall outside the personal services/management safe harbor

may find themselves in a netherworld of legal uncertainty. OIG has addressed such arrangements in a number of Advisory Opinions, which provide the clearest guidance that exists in this area.

OIG guidance regarding marketing and sales agents

OIG has, over a number of years, addressed marketing arrangements, as well as payments to sales agents, in a variety of Advisory Opinions. In particular, the OIG has consistently identified so-called "success fees"[4] and compensation based on a percentage of revenue[5] as problematic. Most recently, the OIG explained its concerns with success fees as follows, regarding a proposal where the "Requestor" would provide management and marketing services for a sleep laboratory provider:

> Marketing fees paid on the basis of successful orders for items or services are inherently subject to abuse because they are linked to business generated by the marketer. Because the Requestor receives a fee each time its marketing efforts are successful, the Requestor's financial incentive to arrange for or recommend the Hospital's sleep testing facility is heightened. The more test orders the Requestor's marketing efforts generate, the more fees the Requestor receives.[6]

As this article will discuss further in the context of the recent sleep laboratory opinions, this conclusion is inconsistent with standard business practice. In virtually any other context, it is a matter of course to structure compensation that incentivizes a service provider to furnish services in an effective manner. OIG seems to recognize the customary and legitimate role marketing plays in the health care industry, but it has clear concerns if the marketer is paid in a manner that reflects the actual quality of marketer's services, even when the marketer is not in a position to refer patients, and even when the marketer is not in a special position of influence with respect to recommending the provider.

OIG, however, has acknowledged that greater concern arises out of marketing arrangements where the marketer is in a special position of influence. In a series of Advisory Opinions, the OIG has listed elements of what it considers to be potentially suspect marketing arrangements. These include marketing directly by providers and suppliers (particularly what the OIG refers to as "white coat" marketing by health care professionals, including physicians), because they are in a position of trust and may exert undue influence.[7]

Additional suspect elements that the OIG has identified include:

- The degree to which the marketing activity may be coercive, or perceived to be coercive;[8]
- Direct contact between sales agents and physicians in a position to order covered items or services;[9]
- Direct contact between sales agents and beneficiaries;[9]
- Marketing items or services for which there is a likelihood of overutilization (e.g. sleep laboratory testing services);[10]
- Marketing or promotional activity focused on federal health care program beneficiaries;[10] and
- Marketing of items or services that are separately reimbursable (i.e., not included in a bundled or composite rate).[9]

It is not clear how many of these factors need to exist before the OIG will decide the arrangement presents a significant risk of abuse. Certain of these factors seem more pertinent than others. With most of these elements, the OIG's concerns regarding the risk of improper influence are readily understandable. For example, the fact that marketing may be "coercive" seems to be a substantial sign of potential abuse. Here, the OIG explained that, "for example, door-to-door marketing, telephone solicitations, and direct mailings are more intrusive, and typically pose a greater potential for abuse, than truthful passive advertising in general circulation newspapers or on television."[11] (However, one may question the extent to which direct mailings could possibly be considered "coercive.")

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On the other hand, the mere fact that a service is separately reimbursable should not by itself render a marketing arrangement suspect. It is clear that a provider has a financial incentive to increase use of a separately reimbursable service, and it therefore may be likely to put special emphasis on marketing that service. However, that does not necessarily mean that the provider (or its marketing agent) will assert improper influence to encourage beneficiaries to obtain that service or, worse, seek to furnish that service when it is not clearly medically necessary. As with its overriding concern regarding "success fees," the OIG seems to assume that any time a provider stands to gain financially from rendering services, it is more likely to engage in (or incentivize its marketer to engage in) improper activities. Similarly, merely because a particular marketing activity is focused on Medicare patients does not necessarily signal potential abuse; rather, the provider may simply be undertaking community outreach and education geared towards a higher risk population.

Recent sleep laboratory opinions

In two Advisory Opinions concerning sleep testing laboratory services,[12] the OIG has most recently expressed its concern that sleep laboratory testing services "may be particularly susceptible to the risk of overutilization" and its concern with a marketing fee that reflects the successfulness of the marketer's efforts. The facts in the two opinions are similar, except for the manner in which the marketing fees are paid. In each arrangement, a supplier provides equipment and services for a hospital sleep testing laboratory. The supplier also provides marketing, including a part-time marketing manager who visits offices of physicians who are potential referral sources. OIG reached different conclusions depending on whether the marketing fee was fixed or whether it was determined based on how many tests the supplier performed (i.e., a per-test basis).

In one opinion (Opinion 10-24), the compensation was based on aggregate, fixed fees that are consistent with fair market value in arm's-length transactions and that do not take into account the volume or value of federal health care program business—factors the OIG identified as "key safeguards." OIG concluded that it would not impose sanctions, because the fixed fee structure would "mitigate against any undue or additional incentive to generate unnecessary or an increased volume of sleep tests."

In contrast, the OIG declined to approve the structure under which the supplier receives a per-test fee (Opinion 10-23). OIG stated that "because the Supplier receives a fee each time its marketing efforts are successful, the Supplier's financial incentive to arrange for or recommend the Hospital's sleep testing facility is heightened." However, the OIG's concern went beyond this. OIG further stated that "per-click" fee structures are inherently reflective of the volume or value of services ordered. Although this statement is undeniably true, it ignores the fact that the supplier receives the same fee regardless of whether its marketing efforts generated the referral or the referral came completely irrespective of the supplier's efforts.

OIG also believed that packaging the marketing compensation together with compensation for general management services in an all-inclusive per-test fee, heightened the potential risk, because this packaged fee prevented "the transparent assessment of the marketing services provided and the compensation paid for them."

Broader implications for marketing

OIG's unwillingness to approve the per-test fee scenario does not necessarily mean that the OIG concluded the arrangement is unlawful. Instead, the OIG had sufficient concerns such that it could not "conclude that the Arrangement poses a sufficiently

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low level of risk that [it] should protect it." As noted above, the OIG's reasoning is open to question. However, as a practical matter, providers need to take the OIG's position carefully into account when they structure and evaluate any proposed marketing arrangement. Providers may wish to consider the following steps in order to reduce the inevitable legal risk that marketing arrangements present.

- **Fair market value determination.**

Providers should carefully document the means by which they determined the proposed amount and methodology of compensation to marketers is fair market value, particularly where compensation reflects success of marketing efforts. The strongest documentation can be obtained by engaging an independent valuation expert. In all cases, factors to examine may include (1) the expected costs the marketer will incur; (2) the expected time the marketer will expend, and a fair market value hourly rate for these services; (3) excluding any referrals generated directly by the marketer (e.g., by a medical director that the marketer furnishes as part of a broader range of services for the provider) from the compensation formula; (4) the expected costs to the provider if it performed the marketing services itself; (5) fees paid in similar arrangements, to the extent the parties have this information; and (6) fee quotations the provider obtains from other potential marketers.

- **Compliance program and contractual protections.**

In order to reduce the risk of improper activities, providers should require, in writing, that marketers abide by the provider's compliance program and procedures. Among other elements, this should require marketers to utilize only truthful and accurate materials, and to ensure that its staff is adequately trained to make communications that are accurate and non-coercive. Further, the marketer should be contractually obligated to indemnify the provider for any failure to abide by the written contract (including the foregoing requirements), the provider's compliance program, or applicable law. Finally, the provider should immediately investigate any complaints of possible impropriety by the marketer, whether those complaints arise from the provider's own staff or from the community.

- **Review of marketing materials.**

The provider should consider requiring and performing prior review of all written marketing materials. If questions arise as to the propriety of any materials, the provider should consult legal counsel. Similarly, the provider should consider requiring written, preapproved "scripts" for any marketing presentations and telephone calls.

Conclusion

Although it may be difficult or impractical to structure an arrangement to be risk-free (other than those rare arrangements that meet the safe harbor), prudent structuring, documentation, and monitoring can give providers considerable comfort in implementing marketing arrangements that are effective and beneficial, while at the same time not posing undue legal risk. ■

1. 56 Fed. Reg. 35952, 35974 (6/29/91).
2. 42 C.F.R. §1001.952(d)
3. 42 C.F.R. §1001.952(d)(3).
4. See, e.g., Advisory Opinions 03-08 (4/10/03), 08-19 (10/29/08).
5. See Advisory Opinions 99-3 (3/16/99), 98-10 (8/31/98) and 98-4 (4/15/98).
6. Advisory Opinion 10-23 (10/28/10).
7. See Advisory Opinions 99-12 (11/23/99), 99-3 (3/16/99) and 08-19 (10/29/08).
8. See Advisory Opinion 99-8 (7/6/99).
9 See Advisory Opinions 99-3 (3/16/99) and 98-10 (8/31/98).
10. See Advisory Opinion 99-8 (7/6/99).
11. See Advisory Opinion 99-8 (7/6/99). See also 56 Fed. Reg. 35952, 35974 (6/29/91).
12. Advisory Opinions 10-23 and 10-24 (both issued 10/28/10).