OIG Approves Web-Based Advertising and Care Management Incentive Programs with Restrictions

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Background

On August 30, 2002, the Department of Health and Human Services Office of Inspector General ("OIG") published Advisory Opinion 02-12 concluding that it would not impose sanctions on a vendor's disease or care management program that provides incentives to patients and physicians or on a vendor that advertises to patients on its website.

The company that requested the opinion is a vendor of services provided to enrollees of health plans, insurance companies and employer health plans. These disease or care management services are focused on behavior modification and compliance with drug regimens. In addition to providing these services the vendor also intends to provide advertising on its website.

The opinion is important for two reasons: 1) it allows for certain types of compensation to reward patient compliance with disease or care management programs and to compensate the patient's physician for assisting the vendor; and 2) it allows for the sale of advertising on a vendor's website.

Disease or Care Management Programs

Disease management, care management and other similar programs have become a popular means of assisting patients by educating them on diet, drug compliance, exercise, lifestyle changes, and other health improvement strategies. However, participation in and compliance with these programs is difficult to ensure. So, while these programs are seen by many as a way to enhance quality of life and health, the feeling is that patients do not sufficiently avail themselves of or participate in the programs. Because the vendor may be paid based on its demonstrated success in improving the health and reducing the costs of the managed care enrollees, the vendor needs tools to allow it to get the attention of the enrollees and physicians. Simply sending a person a written description of the program may not be enough. Disease management vendors have been aware that providing something of value to a patient or a physician may violate federal or state anti-kickback laws. Therefore, these vendors have struggled to find other ways to encourage participation and compliance. This Advisory Opinion is important in describing the legal ways to allow such incentives to be paid to enrollees and physicians.

Description of Vendor's Program. The program described in the Advisory Opinion would use Internet-based methods to remind and encourage patients to take medications, refill prescriptions, and comply with "behavior modification" regimens prescribed by their physicians. The vendor contracts with managed care organizations ("MCOs"), such as health maintenance organizations, insurance companies and employer-based health plans to provide these services to the MCOs' enrollees. The vendor is paid by the MCO; the enrollee does not pay for any of the costs of the program. The vendor may be compensated in either of two ways: 1) a fixed fee (paid based on the number of persons enrolled in the vendor's program) or 2) a portion of the MCO's savings that result from improved compliance, as measured by predetermined benchmarks. Without comment, the OIG noted that the vendor certified that the fees in either case would be consistent with fair market value in an arm's length transaction.

Like many of these programs, this program relies on the MCO to identify those enrollees who may be eligible for the program. Eligibility might be determined by diagnosis or procedure codes that indicate if the enrollee has a chronic illness or is hypertensive, two of the eligibility criteria under the vendor's program. Once identified, the vendor contacts the individual and, if the individual elects to enroll, the vendor directs the enrollee to the vendor's secure website, where the enrollee may interact with the vendor. An integral part of this
interaction includes an incentive system that rewards enrollees for taking prescribed drugs and modifying behavior to improve health (e.g., less salt in the diet). In return for compliance, the vendor awards points for taking the desired actions. These points would be redeemable for goods and services. The points would not be used for goods and services reimbursable by a federal health care program. Other than the points, nothing of value would be provided to the enrollee.

Also, the program allows the enrollee to involve his or her physician in order to encourage the physician to provide input and feedback regarding the enrollee's clinical progress. The physician would not be able to use the vendor's website to prescribe or diagnose. The physician would earn points for participation in the program (e.g., points would be awarded if the physician reviews the enrollee's information and compliance results). No points would be awarded to a physician for ordering or providing an item or service to a patient. The points would be redeemable under the same rules that apply to enrollee point awards and the physician would not receive any other type of compensation from the vendor.

Other important provisions of the vendor's program:

- Enrollee is free to fill or refill prescriptions at any pharmacy.
- There are no points or other financial rewards for purchasing drugs from a particular pharmacy.
- The program will not affect the enrollee's cost sharing obligations for drug purchases and the vendor is not involved in determining enrollee cost sharing obligations.

**OIG Analysis.** While the OIG indicates that the program could potentially generate prohibited remuneration under the anti-kickback statute if the intent to induce or reward referrals were present, and may violate the beneficiary inducement statute, the OIG determined that it will not impose sanctions on the vendor's program for the following reasons:

- The payments by the MCO to the vendor should not implicate the anti-kickback statute because the vendor's services do not include the provision, referral or recommendation of federal health care program business.
- Vendor's payment of points to the physician is not intended to induce the physician to order, refer or recommend the purchase of items or services reimbursable by a federal health care program. Rather, the physician is compensated for specific compliance activities that are not covered under a federal health care program.
- Vendor's payment of points to the enrollee is not intended to induce the beneficiary to order an item or seek reimbursement under a federal health care program. Rather, the enrollee is compensated for complying with the program. Compliance is not covered under a federal health care program.
- To the extent that items or services reimbursable under a federal health care program (e.g., prescription drugs or physician services) are ordered as a result of the enrollee's treatment regimen, they are only tangentially related to the compliance activities. The vendor does not supply or otherwise profit directly from the goods or services and has no other financial relationship with the physician or enrollee for federal health care business.
- Because the services and products redeemable with the points are not reimbursable by a federal health care program, there is no need to determine whether the agreements between the vendor and the suppliers of the redeemable goods or services (e.g., airline tickets) may violate the anti-kickback or beneficiary inducement statutes.

**Web Advertising**

Advertising on the World Wide Web has become commonplace. However, payments for placing these advertisements may implicate the fraud and abuse laws when they describe items or services reimbursable under a federal health care program. The anti-kickback law is implicated even when payment is made to "recommend" a product or service.

**Advertising Program Description.** In addition to providing the disease or care management program, the vendor intends to sell "banner" advertising on its website; "hyperlinks" for pharmacies participating in the MCO's provider network; and pharmaceutical company sponsored "chat" rooms for interactive discussions. The vendor's contract with an advertiser would be clear as to the type of advertising, the terms and conditions of the advertising, and the fee. The fee would be fixed and would not fluctuate based on the value, quality, quantity, or content of any sale transaction and would be consistent with fair market value.

Any advertising on the vendor's website would meet the following vendor requirements:

- Clearly identified as advertising. There would be no confusion between the vendor's web content and the advertising.
• A disclaimer that the vendor's inclusion of the advertising on the website does not constitute a guarantee, endorsement or recommendation of the product or service advertised.

• Advertisers would be prohibited from implying that the vendor endorses or has co-branded the service or product.

• Vendor would not have any exclusive arrangement to advertise and would seek to contract with anyone who might be interested.

• The advertisers would be required to comply with the requirements of the Health on the Net Foundation Code of Conduct.

In addition to the above, the vendor would sell banner advertising to health care and non-health care advertisers for a fixed, pre-determined amount. The advertising may include hyperlinks. Pharmacies that purchase banner advertising may also purchase hyperlinks to their own websites. The enrollee would have access only to advertising and hyperlinks for pharmacies participating in that enrollee's particular provider network. The fee would be a "per click" or a flat fee per purchase (the flat fee would not vary with the value of the order). The vendor would require the following with respect to the pharmacy websites that are hyperlinked:

• Enrollee must affirmatively click on a link in order to be sent to a pharmacy's web page.

• Enrollee must have the ability to go directly back to the vendor's website (e.g., using "back button").

• In order to promote informed decision making, a pharmacy will require the enrollee to take affirmative action to make a purchase and will allow the enrollee to review the purchase terms prior to completion of the transaction.

• In addition to pharmacy advertising and hyperlinks, the vendor's web page must offer a listing of all participating pharmacies. The list may include hyperlinks. The vendor will not solicit nor accept payment from a pharmacy to be included on this list.

**OIG Analysis.** The OIG confirms that the vendor's advertising program implicates the anti-kickback law because Internet advertising by a health care provider may create the impression that the host (vendor) is "recommending" the advertiser's products to its enrollees. However, with some concerns, the OIG concludes that it will not impose sanctions with respect to the vendor's advertising program for the following reasons:

• The advertising on the vendor's web page is comparable to print media advertising in general circulation media which typically does not implicate the anti-kickback law for the following reasons:
  • Advertising is passive, requiring consumer to contact the advertiser directly to purchase something;
  • Advertising itself is separate from the website's content and indicates that it is "paid" advertising; and
  • With respect to a pharmacy advertising with a hyperlink, the pharmacy agrees to ensure that any purchase is voluntary.

• The advertising is not targeted to enrollees covered under federal health care programs.

• Website advertising clearly indicates that the vendor does not recommend the advertised product or service.

• "Per click" or "per purchase" fees paid by advertisers are fair market value and do not vary based on the volume or value of business generated by the advertising.

• There is a requirement to separately list all pharmacies on an enrollee's personal web page. Pharmacies would not pay to be included on this list.

• Sponsorship of "chat rooms" needs to be clearly identified as such and vendor (not sponsor) must exclusively control editorial content and operation of the chat room. Sponsorship fee would be fixed and at fair market value.

Finally, the OIG cautions that misleading advertising or improper steering of chat room discussions could lead to illegal manipulation which would not be protected under the Advisory Opinion.

**Conclusion**

The Advisory Opinion is very helpful to those organizations looking to encourage good behavior that will enhance the quality of life and reduce health care costs. Further, the OIG's approval of web page advertising and sponsorship (with restrictions) should assist with the dissemination of information to enrollees. However, a few final points should be made:
Disease or Care Management Programs:

- Vendor’s program services and the compliance activities are not reimbursable under a federal health care program.\(^9\)
- Vendor services and the compliance activities do not generally result in the recommendation or referral of services or items covered under a federal health care program.
- Ordering of federal health care program products or services is controlled by physicians and pharmacies who are compliant with state and federal laws with respect to such orders.
- Ordering of products or services by a physician or enrollee does not benefit the vendor.
- Referral of any business to the vendor does not involve federal health care program reimbursement to the vendor.
- Points are not redeemable for services or products reimbursable under a federal health care program.

Web Advertising:

- All advertising and sponsorship on the website are clearly separated from substantive website content.
- Payment to the vendor is not related to the volume or value of products or services ordered as a result of the advertising.

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Gardner Carton & Douglas has assisted several disease management and other health care service companies with the development of websites and disease/care management programs. We have analyzed legal issues such as any anti-kickback implications that arise from these endeavors. We have also offered our advice with respect to websites in a manner that takes into consideration other issues such as website accreditation, intellectual property, FTC regulation, privacy laws and other relevant issues.

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1 Please note that an Advisory Opinion may not be relied on as legally binding on any person other than the requestor of the opinion. 42 C.F.R. 1008.53. However, Advisory Opinions are obviously helpful in determining how the federal fraud and abuse laws may be interpreted by the enforcement authorities.

2 Typically the requestor's name and other identifying information are removed from published Advisory Opinions.

3 The Advisory Opinion specifically offers no opinion about the application of state and federal health information privacy laws, including the recently finalized Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). The concern is that the MCO’s use and disclosure of health information in order to identify persons eligible to participate in the program must meet the restrictions of the various privacy laws. Under HIPAA, these activities will usually be permitted as “health care operations” of the MCO.

4 Sections 1128B(b), 1128(b)(7) and 1128(a)(7) of the Social Security Act.

5 Section 1128A(a)(5) of the Social Security Act.

6 This Advisory Opinion is similar to a prior disease or care management Advisory Opinion (00-4) which found that the program at issue would not increase federal health care costs because the costs would be paid by the individuals or their employers. To the extent that Medicare+Choice plans contracted with the vendor, the OIG’s concern was minimized because the plans were paid a fixed (“capitated”) rate that would not increase because of the vendor’s program; the OIG also noted that the program offered “significant benefits to individuals with chronic disease”.

7 It might be argued that the points are paid to the physicians and enrollees in exchange for business referred to vendor. However, according to the OIG the vendor services are not reimbursable under a federal health care program.

8 The OIG assumes that prescriptions and dispensing of medications will comply with all federal and state laws, including that the prescribing physician and dispensing pharmacy will comply with the law of the state where the patient resides.

9 Advertising of drugs that are controlled substances would be prohibited, as required by federal law.

10 If disease management services are eventually approved as a covered benefit under a federal program, then payments to enrollees and physicians under such a program will need to be reviewed for compliance with the anti-kickback and beneficiary inducement laws.
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