Legal Corner

Medicare Part D Means Increased Anti-kickback Law Exposure

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Introduction

In *MPM*'s inaugural issue, a colleague of mine addressed what practitioners need to know about the Medicare Part D prescription drug program in order to answer questions their patients were likely to ask.[1] In this issue, I address how the Medicare Part D program increases physicians' exposure under the federal Anti-kickback Statute, and what they should do to reduce or eliminate that increased exposure.

The Anti-kickback Law: An Overview

The federal Anti-kickback Statute bars the knowing and willful solicitation or receipt, and the knowing and willful offering or payment, of "remuneration," directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce referrals for, or purchases of, items or services for which payment may be made in whole or in part under a federal health care program (such as Medicare or Medicaid). However, this statute prohibits much more than what are classically thought of as kickbacks, bribes, and rebates. Remuneration has been interpreted to include gifts, discounts, the furnishing of supplies or equipment, credit arrangements, cash payments, loan forgiveness, and any other form of benefit tied to the making of a referral or purchase. Remuneration violates the statute if a single purpose of that remuneration is the inducement of a covered purchase or patient referral, even if this is not the primary purpose of the payment.

The statute also prohibits "knowing and willful" conduct. The government's position has been that this level of intent can be inferred from the circumstances.

The statute and regulations applying it contain exceptions and so-called "safe harbors" for particular types of arrangements, such as written employment agreements and personal services agreements, among others, that strictly comply with specified standards. Violation of this law can result in the imposition—on both the maker and recipient of the remuneration—of huge civil monetary penalties, criminal prosecution (leading to fines and imprisonment), and exclusion from Medicare, Medicaid, and other government health programs.

The Anti-kickback Statute and Pharmaceutical Marketing

The Anti-kickback Statute applies to remuneration offered, paid, requested, or received for recommending or prescribing any item—*including pharmaceuticals*—to the extent that they may be paid for by Medicare, Medicaid, or certain other programs. While this has been the case ever since the Anti-kickback Statute was adopted about 20 years ago, for many years, the pharmaceutical industry and many physicians largely ignored this law as it affected the dealings between them. In the last few years, however, there have been quite a number of high profile enforcement cases involving the Anti-kickback Statute as applied to pharmaceutical company marketing activities, with some involving physicians. A common practice has been for the government to settle its action against the pharmaceutical company and then bring enforcement actions against the individuals involved—both sales representatives *and physicians*.

You may already be aware of this new development. Partially in response to this situation, the American Medical Association (AMA) has revised its Ethical Guidelines (see AMA Guideline E-8.061, "Gifts to Physicians From Industry") and created a CME course on this topic. The Office of Inspector General (OIG) of the Department of Health and Human Services issued "Compliance

Guidance" for the pharmaceutical industry, and separates such guidance for physicians and physician practices. Various industry associations, such as the Pharmaceutical Manufacturers Association, adopted voluntary industry codes of conduct, such as the "PhRMA Code," intended to modify the historic marketing practices used by pharmaceutical companies that try to encourage physicians to prescribe their products. In addition, several states have passed laws that limit and require the reporting of all gifts and payments that pharmaceutical companies give to physicians.

The Impact of Medicare Part D

Before Medicare Part D, there were many physicians who could mostly ignore the Anti-kickback Statute in their relationships with pharmaceutical companies. This was because the law related only to inducements of prescriptions of items and services for which federal health care programs might be the payor. Medicaid paid for pharmaceuticals; however, with certain narrow exceptions, Medicare did not. Thus, if a physician did not participate in Medicaid or other federally covered programs, and did not practice in the narrow areas in which Medicare might pay for certain drugs, he or she basically did not have to worry about this law when doing business with pharmaceutical companies.

Medicare Part D has changed everything. Under Medicare Part D, the general rule is that Medicare pays for prescription drugs. Medicare is considered to be paying for the drugs under this law even though the patient's drugs are paid for through a Medicare drug plan operated by a private corporation. In addition, the rule applies despite the fact that the beneficiary pays a premium to the plan, Medicare also pays the plan and, thus, is paying part of the cost of the drugs.

Providers are directly affected because a large segment of their patient population is, or soon will be, enrolled in a Medicare prescription drug plan. This means that providers should immediately make certain that their relationships with pharmaceutical companies comply with the law.

Pharmaceutical Marketing Techniques That Are Illegal or Risky Under the Anti-kickback Statute

Pharmaceutical companies have been very creative in seeking to influence prescriber behavior. Some of their activities are perfectly legitimate. Others are not. Providers should pay attention to the marketing practices by pharmaceutical representatives and refuse approaches that are illegal or appear to be high risk.

Illegal or Apparently High-risk Marketing Practices

Examples of the most blatant misconduct

In 1994, the OIG published a "Special Fraud Alert," entitled *Prescription Drug Marketing Schemes*, listing common marketing methods then in use that violated the Anti-kickback Statute. The methods described include such things as:

- "Product conversion programs" that financially rewarded a pharmacy or physician each time a patient was converted from one company's product to another company's product
- "Frequent-flier programs" in which physicians earned points toward airline frequent-flier mileage each time they completed a questionnaire for a new patient placed on the company's drug product
- "Research grant programs" in which physicians were given substantial payments for de minimus record-keeping tasks related to each patient prescribed the company's drug product

As of 1994, pharmaceutical company methods were fairly blatant, along the lines of the examples just set forth. In these examples, the very structure of the incentive included the proof of the criminal intent to induce referrals and/or prescriptions.

Examples of more recent, more subtle, but still dangerous conduct, based upon the use of prescriber databases

Since the mid-1990s, pharmaceutical companies have become much more sophisticated in their marketing approaches. They now purchase prescription records from companies

that aggregate the data from pharmacy chains. These records do not include patient names and often do not include physician names, but do include DEA numbers. The pharmaceutical companies obtain the prescribing physicians' names by renting the AMA's "physicians' master file" (which includes the DEA numbers and the corresponding physician names). This gives the drug companies a database that reveals in detail the prescribing habits of individual physicians, informing them of which physicians are heavy prescribers of their products, and which are ripe targets for aggressive marketing because they are heavy prescribers of competing drugs.

In addition, pharmaceutical companies can track changes in prescribing habits over time. Because they have this information, the companies no longer have to use the heavy-handed and obvious approach of explicitly conditioning payment on the number of patients prescribed their drugs. However, enforcement authorities are aware of these databases, and take the position that the use by a company of such a database to target the provision of certain benefits to physicians proves the marketing motive behind the provision of those benefits and, thus, can be used to prove criminal intent under the Anti-kickback Statute. Therefore, certain methods used today that do not explicitly require the physician to place a patient on a company's product still may be held to violate the Anti-kickback Statute. Examples discussed at recent seminars on enforcement efforts in this area, all involving physicians selected because of their status as heavy prescribers of a company's or their competitor's products, included the following:

- Providing free trips to luxurious resort locations for the target physician and his/her spouse to attend "seminars" on the company's products
- Hiring a physician as a "consultant" or "lecturer," where little effort is required of the physician
- Paying a physician for time spent listening to marketing presentations
- Providing meals or other items of significant aggregate value to a physician or practice
- Paying a physician to train the marketing person, when the "training" is being purchased over and over and exceeds what the marketer legitimately needs in order to do his or her job
- Providing drugs free or at reduced prices for the physician or members of his/her family;
- Providing drugs free or at reduced prices, where the physician may be expected to bill payors at the average wholesale price or market price for the drugs
- Paying for physician services of any kind at more than fair market value for the time, effort, and expertise required

What Should Providers Do to Reduce or Eliminate Their Compliance Risk?

Tip #1: Use These Key Principles to Help Identify Potential Areas of Legal Risk in Your Relationships With Pharmaceutical Companies

1) Does the marketing method involve providing anything of value, in cash or in kind? If so, is the value more than de minimus, both in terms of each item and in the aggregate? What is the nature of the item provided? For example, is it something like pens and notepads for the office or a medical textbook (more likely to be acceptable), or something like free weekly meals for the office staff (less likely to be acceptable)?
2) If you are receiving the item, are you a prescriber or purchaser of the company's products or are you in a position to influence the prescribing or ordering practices of others? Examples include, but are not limited to, physicians and others who may write prescriptions, persons who decide what items are placed on the formulary of a health care facility or managed care plan, pharmacy benefits managers, and purchasing agents.
   OR
   Is the recipient of the item in your immediate family?
   OR
   Is the recipient of the item an entity favored by you or your family, such that a contribution or benefit to the entity will benefit you or your family? Examples include your favorite charity and your employer.

3) Is something of value, in cash or in kind, being provided in exchange for items or services legitimately needed by the company, and are these items or services of comparable fair market value? Are the items and services really being provided to the company or is the transaction a sham to cover the payment of something of value to the company?

If the circumstances under which a physician is receiving a payment or benefit are such that a reasonable physician should know that it is not legitimate, the government will take the position that the physician's acceptance of the payment or benefit was a "knowing or willful" violation of the Anti-kickback Statute. The inference will be even stronger if the physician is a heavy prescriber of the company's products or if his/her prescribing patterns shift in the direction of the company's products after receipt of the payment or benefit.

TIP #2: Obey the AMA Guidelines and the PhRMA Code

Government speakers, such as Assistant US Attorney James Sheehan of the US Attorney's Office in Philadelphia, have suggested that strict adherence to the AMA Guidelines and the PhRMA Code will go a long way to keep physicians, as well as those engaged in marketing pharmaceuticals, out of trouble under the Anti-kickback Statute.

- The AMA Guidelines may be located at www.ama-assn.org/ama/pub/category/print/8484.html
- Free AMA educational resources regarding the guidelines, gifts to physicians, and physician relationships with industry may be located at www.ama-assn.org/ama/pub/category/8405.html
- The PhRMA Code may be located at www.phrma.org/files/PhRMA%20Code.pdf

TIP #3: Read the OIG's Guidance for Pharmaceutical Manufacturers and Review Your Relationships With Pharmaceutical Companies for Danger Areas Identified in the Guidance

- The OIG Guidance for Pharmaceutical Manufacturers may be located at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf
- If you find that your arrangements are in any of the danger areas, you may wish to consult an attorney familiar with the Anti-kickback Statute

TIP #4: Opt Out of Third-party Access to Your Data on the AMA "Physicians' Masterfile"

In July 2006, the AMA adopted a policy that permits physicians to opt out of pharmaceutical company access to their prescribing data.

Conclusion

The Medicare Part D program affects all physicians who treat Medicare patients and not just because of patient confusion and questions about the program. Medicare Part D will expose physicians to increased compliance risk under the Anti-kickback Statute. I strongly urge you to review your relationships—even informal ones—with pharmaceutical companies and get yourself into compliance now. The enforcement authorities always have tended to focus on areas involving large amounts of federal program dollars, and have made it clear that enforcement in the pharmaceutical area is a high priority. As noted in this article, their past practice has been to enter into large dollar-value settlements with the big companies and then to go after the individuals, both sales representatives *and physicians*. You do not want to be one of those physicians. MPM

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Reference

1. Manger JA. Medicare Part D: risks and opportunities for practitioners. *Medicare Patient Management.* 2006;1:43-45.