PRACTICAL*HEALTH*LAW

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NOVEMBER/DECEMBER 2008

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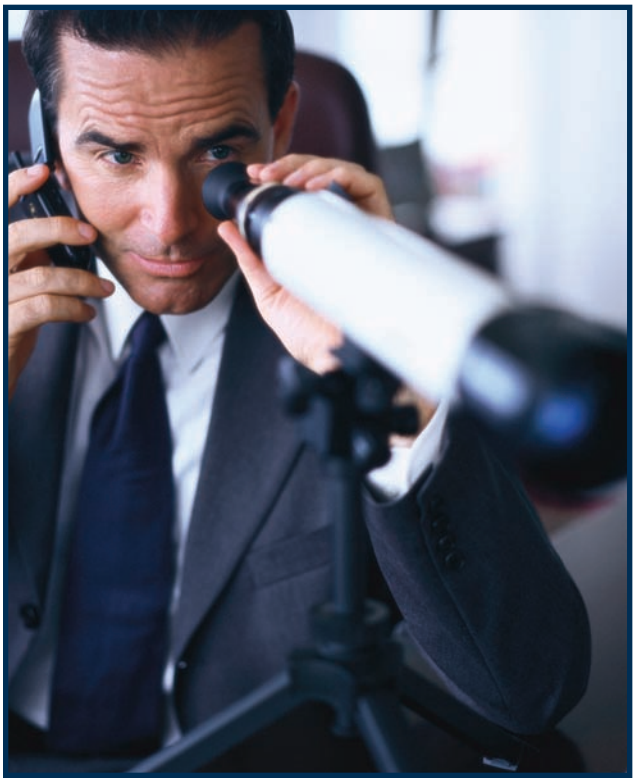
Not all gifts are good

Industry-physician relationships subject to increased scrutiny

The American Medical Association's Code of Ethics states, "Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration."

So how does the health care profession balance this against efforts by biotechnology and pharmaceutical manufacturers to inform physicians about new drugs, devices and other products? In a time of heightened awareness of physician financial relationships and incentives, there's much for you to consider.



THE RELATIONSHIPS

Concerns about the appropriateness of these relationships arise in clinical research settings, institutional product selection and exclusive vendor relationships. But the most recognized area of concern is the individual industry-physician relationship.

The fear is that these relationships will bias physician decision-making in a way that undermines the quality of patient care and unnecessarily increases health care costs. Many associate fraud and abuse risks with these relationships, and physician codes of ethics (as mentioned above) recognize the risk to the physician-patient relationship. In fact, according to a 2003 study appearing in the *Journal of the American Medical Association*, research has revealed that gifts, no matter how small, can cause recipients to lose objectivity and perceive a reciprocal obligation to the gift-giver.

AAMC'S POSITION

The Association of American Medical Colleges (AAMC) recently considered a task force report on developing guidelines to manage industry-physician relationships. This report recommends, among other things, the development of policies that prohibit *all gifts* from industry for physicians, faculty, staff, students and trainees of academic medical centers (AMCs), either on-site or off-site. The report also recommends that the prohibition apply to equipment and service vendors.

According to the report, medical centers should discourage their faculty, students and trainees from:

- Attending nonaccredited industry events that are marketed as continuing medical education (CME),
- Accepting payment for attendance at industry-sponsored meetings,
- Accepting gifts from industry representatives at meetings, and
- Participating in "ghostwriting."

Further, the task force recommends that pharmaceutical representatives not be permitted access to patient care areas; that device representative visits be limited to those who are appropriately credentialed; and that such visits be only at the request of a physician.

PhRMA'S RESPONSE

For its part, the pharmaceutical industry has created its own voluntary set of guidelines on physician financial relationships. In its 2004 *Code on Interactions with Healthcare Professionals*, the Pharmaceutical Research and Manufacturers Association (PhRMA) adopted less stringent guidelines with respect to gifts for physicians and other health care providers.

But in July 2008, PhRMA issued a revised code, effective January 2009. Among the key changes to the code is PhRMA's new prohibition on the distribution of pens, mugs and other "reminder" products. PhRMA notes that such items, while minimal in value, may foster misperceptions that company interactions with health care professionals aren't based on informing them about medical and scientific issues. The revised code also prohibits sales representatives from providing restaurant meals to health care professionals. But it permits occasional meals in a health care professional's office in conjunction with an informational presentation.

CME CONCERNS

To some, pharmaceutical- or biotech-company-sponsored educational activities and programs are ways to promote a company's product and to further bias the clinical decision-making of physician-attendees. To mitigate these risks, the AAMC's task force recommends that it coordinate all industry support for CME through an AAMC central office.

The organization also wants medical centers to audit programs to ensure industry-sponsored CME programs comply with accreditation standards. In particular, the Accreditation Council for Graduate Medical Education (ACGME) recommends that individuals involved in determining the content of an education activity disclose relevant financial interests, and states that failure to do so should disqualify an individual from acting as a CME planning committee member, presenter or author.

> *Research has revealed that gifts, no matter how small, can cause recipients to lose objectivity.*

PhRMA's updated 2008 code recommendations regarding CME are similar. For example, PhRMA recommends that a company separate its CME grant-making functions from its sales and marketing departments and that any subsidy for an educational program be given to the CME provider, who in turn can use the funds to reduce the overall CME registration fee.

PhRMA further states that, when companies underwrite CME, the responsibility for and control of the program's content, faculty, materials and venue belong to the program organizers. Even if asked by the organizer, the company shouldn't provide any advice or guidance regarding the CME content or faculty.

WHAT SHOULD YOU DO?

Over the past few years, some academic centers have already adopted strict no-gift policies that prohibit physicians from accepting any type of remuneration from industry representatives. Most hospitals and organizations have found this type of policy difficult to implement and instead have chosen a middle-of-the-road approach, allowing items of minimal value if they're primarily associated with the health care professional's practice (pens or mugs for office use), while not permitting items that primarily benefit the professional, such as tickets to a sporting event, or cash (or cash equivalents), except as compensation for bona fide services.

But with the AAMC's recent task force report and PhRMA's new, stricter gift policies, it appears the trend is continuing toward fewer opportunities for — and perhaps less tolerance of — influence from pharmaceutical and biotech companies. If you haven't already done so, revisit your financial relationship and gift policies and consider whether more strict rules regarding gifts, meals and CME are appropriate. ❙

Medicare regulations for nonhospital resident rotations

One size may not fit all

A large portion of physician training and graduate medical education (GME) is funded both directly and indirectly by Medicare. Generally, teaching hospitals can claim reimbursement for the time residents spend training in the hospital complex. They can also claim costs for the time residents spend training in independent physicians' offices and freestanding clinics (so-called "nonhospital" locations).

The Centers for Medicare and Medicaid Services (CMS) has expanded hospital documentation requirements for counting the portion of resident time in a nonhospital setting.

THE NONHOSPITAL RULE

Medicare requires hospitals to incur "all or substantially all" of the residency program costs in nonhospital settings to claim the time that residents spend in those settings. "All or substantially all" means 90% of the residency program's total resident and teaching costs in the nonhospital location.

If resident salaries and fringe benefits amount to *more* than 90% of the training costs at a nonhospital site, the hospital may not be required to compensate the site for its teaching physician costs. To prove this, the hospital must still calculate the amount of teaching costs for the nonhospital site to show that the hospital did in fact incur at least 90% of the training program costs at that location. And if the resident costs don't meet the 90% threshold, the documentation will be necessary to determine how much the hospital should pay the nonhospital site.

CALCULATING COSTS

The hospital must state its costs in a written agreement or be able to demonstrate that it paid for the costs associated with nonhospital rotations on a "concurrent basis." Concurrent payment means the hospital makes payments by the end of the third month following the month in which the training occurred at the nonhospital site.

Nonhospital rotation agreements typically include four costs:

1. Teaching physician costs,
2. Costs associated with resident salaries and fringe benefits,
3. Total costs for the program in the nonhospital location, and
4. A calculation of 90% of those costs.

Calculating teaching physician costs and resident costs, however, can be complicated.

TEACHING PHYSICIAN COSTS

Hospitals may not know teaching physician costs in advance. The hospital can estimate these costs based on physician time studies, or, alternatively, the hospital can calculate these figures based on a "proxy" methodology that uses an estimate of:

- The number of hours of nonpatient care GME activities for each week, and
- The teaching physician's salary based on specialty-specific American Medical Group Association (AMGA) national average salary amounts. (AMGA salary amounts are available on the CMS Web site, www.cms.hhs.gov/AcuteInpatientPPS/Downloads/AMGA_2007%20Report.pdf.)

Even with the "proxy" methodology, determining teaching physician costs for nonhospital rotations isn't necessarily a straightforward matter. If a teaching physician receives predetermined compensation for his or her time at a nonhospital site, regardless of the number of patients he or she treats, there's a cost for the teaching physician time spent in nonpatient care direct GME activities, such as supervising residents. Conversely, if a physician's compensation at the nonhospital site is based solely and directly on his or her billings, there's no teaching physician cost associated with the resident rotation.

This scenario is typical for a sole practitioner, but there may be other instances where physicians in a group practice don't receive any predetermined compensation. In either situation, CMS assumes that the teaching physician operates as a sole practitioner, and, thus, the physician costs for training at the nonhospital site are zero.

If there's no teaching physician cost at a nonhospital site, the hospital only has to incur 90% of the resident salaries and benefits to meet Medicare requirements for counting residents' training at that site. To meet these requirements, the hospital's written agreement with the nonhospital site could specify that the hospital will incur "all or substantially all" of the costs of the residency program at that site and that the resident costs meet the 90% threshold.

RESIDENT COSTS

Likewise, resident salaries and benefits must reflect the actual costs for the individual residents training at the site. Because hospitals may not know these actual costs in advance, CMS allows hospitals to use the previous year's amounts as an initial estimate.

Or, the hospital can use resident salaries and fringe benefits for the current academic year and the initial rotation schedules to estimate the resident costs in the nonhospital locations. In either case, the hospital can amend the agreement before the end of the academic year to reflect the actual number and length of resident rotations to the nonhospital site.

DOCUMENTING COSTS

If your hospital has residents who work in nonhospital settings, be sure to document resident costs. Information from resident rotation schedules and payroll should be helpful in doing this.

If you don't have teaching physician costs associated with the rotation, document this by using a physician "attestation" or similar document from the nonhospital site. This document must verify that the teaching physicians don't receive any predetermined compensation.

Although these are generally accepted documentation methods, keep in mind that individual Medicare auditors have some discretion to decide what form or type of documentation is sufficient under the circumstances.

Multiple nonhospital practice locations

Question: If a nonhospital provider, such as a physician group or clinic, owns and operates more than one practice location and residents rotate at each of these locations, does the hospital need a separate agreement for each location? Or is a single agreement with the nonhospital provider sufficient?

Answer: A single agreement *may* be sufficient to document that the hospital incurred all or substantially all of the costs associated with the nonhospital rotations — if the agreement specifies the costs in *each* nonhospital provider location. Although the Centers for Medicare and Medicaid Services (CMS) hasn't directly addressed this issue, commentary in the Federal Register and existing guidance documents, as well as public statements made since the rule's issuance, suggests that a single agreement may meet the nonhospital rotation requirements.

The agreement must specify costs for the individual practice locations and break down those costs according to *each* program that sponsors resident rotations in those locations. For example, the hospital's orthopedic surgery residency program and its family medicine program may both send residents to a private physician's office for an orthopedic clinical rotation. The agreement must specify costs for both programs.

Before deciding whether to use a single agreement, consider that accreditation organizations may also require a written agreement for a nonhospital rotation. Talk with your health care attorney to determine whether it makes sense to consolidate those requirements into a single written agreement. Also, be prepared to answer requests from individual auditors for alternative or "back-up" documentation of individual practice site costs.

STRUCTURING YOUR AGREEMENT

With the vast array of hospital and physician relationships, there's no one-size-fits-all agreement to ensure that all resident time is appropriately counted in the event of a Medicare audit. Accounting for teaching costs of a physician who doesn't receive predetermined compensation in his or her practice is only one of many challenges that hospitals face in structuring these agreements. Contact your health care attorney if you have questions about your residents who spend time in nonhospital settings.

In their shoes

Stark regulations and AMC compensation arrangements

Payments between components of an academic medical center (AMC) aren't always tied to discrete, identifiable services but are nevertheless integral to the AMC's patient care, education and research activities. For example, a teaching hospital may transfer funds to the AMC's faculty practice group to help compensate for indigent care services provided by the group's members. Now the Centers for Medicare and Medicaid Services (CMS) has issued final regulations regarding the "stand in the shoes" provisions of the physician self-referral law (the "Stark law") for these so-called "support payments."

YOU HAVE TO TRY ON SHOES ...

Before issuing the final regulations, CMS indicated that it would treat referring physicians as "standing in the shoes" of their physician organizations in both direct and indirect compensation arrangements. In other words, if a group practice or other physician organization has a direct relationship with a hospital, CMS considers the individual physician members to have that same relationship. Therefore, each member also needs to comply with the Stark regulations, and thus fit into a Stark exception.

This raised concern among AMCs and other industry representatives because, as written, the new rule would mean that certain payments between AMC components and physicians — which previously didn't need to comply with a Stark exception — would now need to comply with a direct compensation exception. In the case of a support payment between a hospital and the faculty group practice, if a physician member now "stood in the shoes" of the practice group, the arrangement between the hospital and the physician would also need to fit within a Stark exception for direct compensation.

... TO FIND THE RIGHT FIT

In late July 2008, CMS issued final regulations that clarify that only a physician who has an ownership or investment interest in his or her physician organization is deemed to "stand in the shoes" of that organization. CMS also clarified that the "stand in the shoes" provisions do *not* apply to arrangements that satisfy the AMC exception.

Is this good news for AMCs? Perhaps. An arrangement that complies with the Stark AMC exception is explicitly exempted from the physician "stand in the shoes" provision. And AMCs that rely on the indirect compensation arrangement exception should be protected because the physicians aren't required to "stand in the shoes" of the practice (assuming they don't have an ownership or investment interest).

An arrangement that complies with the Stark AMC exception is explicitly exempted from the physician "stand in the shoes" provision.

However, AMCs still need to be sure that the financial relationships between the various AMC components are adequately protected from Stark liability. If you intend to meet the AMC exception, identify each of the exception's requirements — as they may be difficult to meet, depending on the particular structure and relationships between components of an AMC.

ALL TIED UP

With the new "stand in the shoes" provision, you'll need to review your compensation arrangements to be sure they comply with the most current Stark regulations. For more information about the final Stark regulations and payments between AMC components, contact your legal counsel.

ARE YOUR LAPTOPS AND SMARTPHONES HIPAA COMPLIANT?

The Health Insurance Portability and Accountability Act (HIPAA) requires covered entities to comply with the act's security rule governing electronic protected health information (EPHI). Two areas of particular vulnerability are the use of:

1. Remote access or transmission, including access to information from home or other locations outside the office, and
2. Portable devices that store and transmit EPHI, including laptops, personal digital assistants (PDAs), smartphones (such as BlackBerry® or iPhone™) and USB/thumb drives.

Earlier this year, the Centers for Medicare and Medicaid Services (CMS) announced that it would visit selected covered entities to ensure they're complying with the rule. CMS's "Security Standards: Implementation for the Small Provider" provides helpful information regarding security rule compliance. It notes that, although laptops, PDAs and other portable devices are integral to office operations, they're often a secondary consideration when assessing the security of physician practice EPHI.

Observe these steps when assessing your use of remote access and portable devices:

- Identify the location of all EPHI within your practice. Consider all information you create, receive, maintain or transmit. This may include workstations in your office, as well as portable devices.
- Determine if your procedures identify all locations of EPHI that you back up. Consider your accounting system, electronic medical records, digital recordings of diagnostic images and any other electronic test results.
- Ensure the integrity of data during transmission and confirm that your security procedures and mechanisms apply to or include portable media transmission.
- Create a standard method of destroying EPHI on equipment, media and portable devices you're no longer using.
- Have a process in place that assigns each user a unique identifier and confirm that the identifier is used to track activity within your information systems, including remote access to those systems.

As part of its initiative, CMS has posted a security rule checklist on its Web site, highlighting areas of vulnerability for EPHI security. You can find it on the Web at www.cms.hhs.gov/SecurityStandard.

A message to our clients and friends:

Hall Render is pleased to provide you with this issue of ***Practical Health Law***. This newsletter will be sent to you bi-monthly compliments of our health law attorneys; each issue will also be housed in the **Articles and Newsletters** section of **www.HallRender.com**.

We understand the value of good information when making sound business decisions. ***Practical Health Law*** is written by Hall Render's health law attorneys, each with extensive experience handling the legal issues of health care providers. We trust the information in each issue will be a valuable resource. Our attorneys stand ready to respond promptly to your questions and needs; please contact us if there are specific topics you would like to see addressed.

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IN Downtown Office: Suite 2000, Box 82064, One American Square, Indianapolis, IN 46282 Ph: 317-633-4884 Fax: 317-633-4878
IN North Office: Suite 820, 8402 Harcourt Road, Indianapolis, IN 46260 Ph: 317-871-6222 Fax: 317-338-3946
KY Office: 614 West Main Street, Suite 4000, Louisville, KY 40202 Ph: 502-568-1890 Fax: 502-568-4878
MI Okemos Office: 2369 Woodlake Drive, Suite 280, Okemos, MI 48864 Ph: 517-706-0920 Fax: 517-347-7855
MI Troy Office: Columbia Center, Suite 315, 201 W. Big Beaver Road, Troy, MI 48084 Ph: 248-740-7505 Fax: 248-740-7501
WI Office: 111 East Kilbourn Avenue, Suite 1300, Milwaukee, WI 53202 Ph: 414-721-0442 Fax: 414-721-0491