

## PROCEED WITH THE SAME OLD PRACTICES WITH PHARMACEUTICAL COMPANIES AT YOUR OWN RISK

By Alexander G. Bateman, Jr.



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The relationships between pharmaceutical companies and healthcare providers have been, and will continue to be, under intense scrutiny by state and federal regulators, investigators and prosecutors. In response, the federal government and the pharma-industry have produced guidelines which can be used by physicians to pattern their practices in a safe way. These guidelines should also be utilized when creating or updating your practice's compliance programs.

In April 2002, the pharmaceutical industry released new guidelines governing what is – and is not – appropriate in relationships with those who prescribe and/or provide their drugs. In the guidelines, the Pharmaceutical Research and Manufacturers of America (PhRMA) advises, “nothing should be offered or provided in a manner or conditions that would interfere with the independence of a health care professional’s prescribing practices.” These voluntary guidelines took effect July 1, 2002.

When the U.S. Department of Health and Human Services released its draft “Compliance Program Guidance for Pharmaceutical Manufacturers” on September 30, 2002, pharma companies, hospitals, health systems and physician groups were put on notice that a comprehensive array of marketing incentives and other sales strategies would be put under the Office of the Inspector General’s (OIG) microscope. Research grants, clinical trials, discounts, consulting and advisory payments, customer gifts and entertainment and educational seminars are all identified in the document as potentially suspect relationships, focusing primarily on potential anti-kickback violations.

The OIG has stated that it will be examining many types of arrangements between sellers, buyers and prescribers of pharmaceutical products to determine whether they contain overt or disguised incentive payments intended to induce physicians to

prescribe a particular manufacturer’s product. Department of Justice representatives have publicly announced their intention to continue to examine both sides of the transaction — manufacturers and physicians — for unlawful actions that leave both sides vulnerable to potential prosecution.

Providers should avoid risky relationships with the pharmaceutical industry. One such relationship, known as Product Conversation Payments or “Push Fees”, occurs when a pharmaceutical company offers a cash award or other benefit (such as frequent flyer miles) to retail pharmacies or pharmacy benefit management companies that, directly or indirectly, help persuade providers to choose or switch from one pharmaceutical product to another.

Physicians and hospitals who are recipients of research funds from pharmaceutical manufacturers are likewise cautioned that, to avoid exposure, they may need to demonstrate that monies received from pharmaceutical manufacturers represent bona fide research payments. The amount of funding received by a provider who accepts a grant should be equivalent to the fair market value of the work actually completed, and the grant award or administration should be independent of all product purchasing decisions. Similarly, pharmaceutical companies should not underwrite (and physicians should not accept) trips to continuing education conferences. An exception may be made if the physician is speaking on behalf of the company’s product or otherwise rendering a legitimate service to the manufacturer. Physicians should also never ask for, or accept, benefits in return for meeting with a sales representative.

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# HIPAA PRIVACY COMPLIANCE: COMPLY NOW OR PAY LATER?

## HHS Issues Procedures For Investigations, Imposition Of Penalties And Hearings

By Jay B. Silverman and Keshia B. Thompson



Jay B. Silverman

April 14, 2003 was the final deadline for most “covered entities” to comply with the Health Insurance Portability and Accountability Act Standards for Privacy of Individually Identifiable Health Information (the “HIPAA Privacy Rule”). Although the United States Department of Health and Human Services (HHS) issued Privacy Rule guidance and modifications, it did not extend this deadline. Most covered entities, including physician practices, hospitals, home

care companies, health insurance companies, as well as many union welfare funds and self-insured employee benefit plans were required to implement their written HIPAA privacy compliance plans on or before April 14.

Covered entities that fail to comply with the HIPAA Privacy Rule are subject to civil and criminal penalties. On April 16, 2003, HHS published a document entitled “Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings.” In this document, HHS indicates that it will use enforcement activities to “promote voluntary compliance through technical assistance.” However, HHS also makes clear that it has the authority to (1) issue “investigative subpoenas and inquiries” in connection with a complaint filed against a covered entity, and (2) assess civil penalties against non-compliant covered entities which may be recovered in federal court. The United States Department

of Justice will be responsible for criminal enforcement of the HIPAA Privacy Rule.

Some covered entities may have underestimated the time required to implement a HIPAA privacy compliance plan, particularly the time required to negotiate and conclude business associate agreements. Others may be unable to interpret and implement generic, boilerplate HIPAA compliance manuals they have purchased. Those covered entities that presently find themselves in a HIPAA haze would be well served to enlist the assistance of professionals versed in the requirements of the HIPAA Privacy Rule as they seek to comply. With proper guidance, a covered entity can efficiently and effectively implement a HIPAA privacy compliance plan.



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### YOU BE THE LAWYER: DOCTOR QUIZ

By Gregory J. Naclerio, Partner and Chair, Health Law Regulatory Department

#### TEST YOUR KNOWLEDGE OF HOW THE LEGAL SYSTEM AFFECTS YOUR PRACTICE... LICENSE... POCKET... AND LIBERTY.

1. Can you pay your billing company 5 to 7 percent of collections for submitting bills?
2. You can only pay your management company the fair market value for services they provide.
3. Can you accept a \$60,000 stipend as Department Chair from a local hospital where you admit patients when, in fact, you provide little to no services?
4. The Office of the Inspector General only investigates and prosecutes hospitals and nursing homes.
5. If asked for an interview by the Office of Professional Medical Conduct, the physician should attend the interview alone.
6. The FBI can only investigate my practice if I bill Medicare, Medicaid or another federal program.
7. Even if convicted of fraudulent conduct, judges don’t send doctors to jail.
8. A physician can compensate a non-physician employee or sub-contractor based upon a percentage of collections generated by that non-physician.
9. I can call my practice the “Pain Management Center of Uniondale.”
10. A mobile diagnostic company business corporation wants to hire a physician to do “reads” of certain tests and will pay \$55 per read. Is this allowed?

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Establishing a healthcare compliance program can be an effective way for providers to protect themselves from prohibited behavior: First, make sure that free drug samples are not improperly billed to payers, which violates the Prescription Drug Marketing Act of 1987, as well as the Anti-Kickback Statute and False Claims Act. Also, the records of the practice should properly reflect all discounts received on drugs and device purchases. Under the PDMA, recipients of samples are prohibited from any form of resale and are required to request samples in writing and provide the manufacturer or distributor with a written receipt. Failure to comply may result in sanctions, which include imprisonment of up to ten years and/or a fine of not more than \$250,000 for selling or purchasing drug samples, and imprisonment of up to one year and/or a fine of not more than \$1,000 for failure to follow the documentation requirements.

Second, a practice should establish stringent protocols for dealing with sales representatives and manufacturers. A set "no gifts accepted" policy is the easiest to enforce. Third, the practice should develop policies and procedures regarding receipt of grant money and participation in clinical trials. Grant money should never be tied to an agreement to purchase or prescribe a particular product. Fourth, a practice should include policies in its Compliance Program Code of Conduct that reflects state laws and regulations regarding the practice and dispensing of medicine.

In conclusion, it is critical that physicians and other healthcare providers assess their financial relationships with the pharmaceutical industry. To avoid dangerous pitfalls in these relationships, an effective and up-to-date compliance program is not only necessary, but serves as a valuable insurance policy.

## RECENT AMENDMENTS TO THE NYS HEALTH CARE PRACTITIONER REFERRAL ACT

By Sandra Maliszewski



Sandra Maliszewski

### LABORATORY BUSINESS PRACTICES (10 NYCRR 34-2)

Recently, the Health Care Practitioner Referral Act (Act) was amended to include a new Subpart entitled "Laboratory Business Practices." It prohibits (1) "health services purveyors" (HSP), their agents and employees from accepting considerations for referral of performance of health services; and (2) labs, their agents, and employees from giving, and HSPs from accepting, consid-

erations for referral of specimens for performance of lab tests. Fee splitting is prohibited.

The provision of equipment, supplies and services at less than fair market value by a lab to an HSP is prohibited with an exception for "directly related equipment, supplies and services."

Rental of space by labs from an HSP (or an immediate family member) must be for the fair market value and not related to the volume or value of tests ordered by the HSP. This provision now includes space for storage of supplies provided by the lab to the HSP. Patient Service Centers (PSC) located and operating within the space of a practice or office of an HSP that refer specimens to the lab operating the PSC are also prohibited. If the PSC is located "in a building in which an HSP that refers specimens to the lab operating the PSC has a direct or indirect ownership, investment or leasehold interest" with certain requirements, then the prohibition does not apply.

The provision of employees by a lab to an HSP as a consideration for referral of specimens is also prohibited. This does not include circumstances where there exists a contract for lab management services, or where there is a written contract with a hospital or an HMO for provision of phlebotomy services or directly related services, nor does this prohibit a lab from providing blood drawing in a person's residence, including nursing homes, under certain circumstances.

The Act also prohibits (1) professional courtesy in the provision of lab services; (2) provision of computers, computer equipment, and/or supplies at below fair market value, unless they are solely and exclusively used for the provision of lab services; (3) the disposal or payment for disposal of medical waste by a lab for an HSP; (4) labs from communicating with patients of referring HSP in the form of recall letters, inclusive of reporting test results except where there exists practitioner authorization for an exact copy to be sent to the patient; (5) the routine waiver of co-payments, coinsurance, deductibles and/or fees by a lab for test services to patients of a referring HSP; and (6) financial relationships or loans between referring HSP and a lab to which they refer specimens if such relationships are secured/facilitated by or through the efforts of the lab. Labs are now required to maintain documentation to evidence compliance with these regulations. Lastly, exceptions to direct billing of the HSP by labs are outlined as well as a clarification that any payment or billing transaction authorized by direct billing law is not rendered illegal.

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## YOU BE THE LAWYER: DOCTOR QUIZ

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### ANSWERS:

1. **No.** The Health Department says it's "fee splitting." You can only pay your billing company the fair market value of its service (i.e., x-dollars per claim).
2. **True.** To do otherwise also violates the "fee splitting" rule.
3. **No.** You may be violating the Federal Anti-Kickback Statute, which is a felony.
4. **False.** The OIG also investigates individual physicians and other health care providers who bill a federal health insurance program.
5. **False.** This is a "critical event" in the OPMC process and the physician should consult counsel prior to attending the interview.
6. **False.** Since August 1996, the Federal Government prosecutes, as a federal felony, any entity that defrauds any "health care benefit program."
7. **False.** The federal sentencing guidelines demand jail in certain instances and doctors do go to jail.
8. **False.** A physician can only compensate another physician based on productivity.
9. **No.** Only a licensed Article 28 Facility can use the term "Center."
10. **False.** A business corporation cannot pay a physician for medical services.



## ABOUT THE FIRM

Founded in 1968, Ruskin Moscou Faltiscek, P.C. has grown into one of the most respected and largest multi-practice law firms in the New York metropolitan area and is headquartered in Uniondale, New York. With over 60 attorneys in 18 practice areas, the firm offers innovative legal services, keeping focus on the client's goals, in the areas of corporate & securities, corporate governance, employment, energy, environmental, financial services, banking & bankruptcy, health law, intellectual property, life sciences, litigation, municipal & regulatory affairs, real estate, construction, seniors' housing, technology, trusts & estates, and white collar crime & investigations. Clients include large and mid-sized corporations, privately held businesses, institutions and individuals.

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