Winter (January) 2005 Volume 8 Issue 1

Physician Organizations

A Publication of the American Health Lawyers Association Physician Organizations Practice Group

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AMERICAN HEALTH LAWYERS ASSOCIATION

Leading Health Law to Excellence through Education, Information, and Dialogue

Physicians, Pharmaceuticals, and Fraud: Navigating the Mine Field

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I. Introduction

In 2001, TAP Pharmaceuticals pled guilty to a charge of conspiring to violate the Prescription Drug Act, Federal Anti-Kickback Statute, and the False Claims Act. As part of the plea, TAP agreed to pay a total of $875 million in criminal fines, civil penalties, and false claim reimbursements.[1] The charges related to TAP's marketing and pricing of Lupron, a cancer drug. The government asserted that TAP knowingly distributed free samples of Lupron to doctors, who were then filing claims for reimbursement from Medicare. Additionally, the government charged that TAP was reporting a much higher average wholesale price to the Department of Health and Human Services (DHHS) than it was actually receiving from physicians. Thus, because physicians were reimbursed at the artificial average wholesale price, they were pocketing the difference between the average wholesale price and the discounted rate they were actually receiving (and in the case of the free samples, physicians were pocketing the entire average wholesale price). The government investigation revealed a culture of abuse at TAP. It found that TAP had conspired with physicians to report higher than charged prices for Lupron, and aggressively marketed this scheme to increase physician compensation as a means to increase use of Lupron and generate revenue for the company.

In November 2004, Dr. John Romano became the fifth doctor convicted as a result of the TAP Pharmaceuticals investigation. Dr. Romano filed for reimbursement under Medicare even though the Lupron he administered was provided to him as free samples. Romano could receive up to ten years in prison for his role in the TAP scandal. The previous four physicians who were convicted only received probation, but were fined and excluded from participation in federally-funded healthcare programs, effectively ending their medical careers.

In another recent settlement that garnered great publicity, Pfizer, Inc. agreed to pay $430 million in criminal and civil fines, and pled guilty to charges that a subsidiary illegally advocated and promoted "off-label" use of the drug, Neurontin. Although Neurontin was only approved for the treatment of epilepsy, Parke-Davis and Warner-Lambert (Pfizer had acquired Warner-Lambert and its subsidiary Parke-Davis) were promoting it as safe and effective for such non-indicated uses as pain relief, headache treatment, and controlling bipolar disorder. In this action, the government supported the allegations of former Pfizer scientist David Franklin, who filed a qui tam action against Pfizer. Franklin and the government alleged that Pfizer actively encouraged exaggerations and lies about Neurontin's effectiveness for off-label indications. In their allegations, they charged that Pfizer paid physicians lavish speaker fees and paid for attendance and travel to sporting events and other entertainment in return for using their names on the by-lines of various studies touting Neurontin's suitability for many diagnoses that were without clinical support.

These two recent enforcement actions are the largest-ever settlement agreements between pharmaceutical manufacturers and the government entities that regulate them. Although these were clearly cases of egregious conduct, the government continues to focus enforcement activity upon the highly lucrative pharmaceutical industry and its relationships with healthcare providers.[2] The penalties for violations are huge: fines, jail time, and exclusions from participation in federally-funded healthcare programs. Therefore, pharmaceutical prescribers are advised to reconsider (and reconsider again after seeking legal counsel) any arrangements or interactions with pharmaceutical companies.

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II. Current Enforcement Initiatives and Focus

In the Fiscal Year 2005 Work Plan, the DHHS Office of Inspector General (OIG) stated that it will continue to focus on healthcare fraud. In particular, the Office of Investigations announced that investigative efforts in the area of Medicare and Medicaid Fraud will "investigate business arrangements that violate the Federal health care anti-kickback statute."[3] Specifically, the OIG stated that focus areas will "include pharmaceutical fraud." Working jointly with such partners as the Drug Enforcement Administration and State and local authorities, OIG will continue to identify and investigate illegal schemes to market, obtain, use and distribute prescription drugs. "By investigating these schemes, OIG aims to stop the inflating of drug prices common in the pharmaceutical industry, [and] protect the Medicare and Medicaid programs from making improper payments."[4] The OIG also said it would be assessing "FDA's oversight and review of allowable promotion of off-label drug uses by drug manufacturers and describe FDA's oversight and enforcement of prohibited promotion of off-label drug uses by manufacturers" as well as looking at disclosure of financial interests by clinical investigators.[5] When a drug is prescribed "off-label," the physician is prescribing it for a use other than that for which it has been approved by the Food and Drug Administration (FDA) as safe and effective. Because of the cost of seeking FDA approval, many drugs are commonly prescribed "off-label," and in fact often have greater efficacy for such non-indicated uses. Nevertheless, as the Pfizer settlement shows, the temptation to exaggerate the efficacy of off-label uses and to pay physicians to support such claims remains and will be a subject of government enforcement action.

III. Federal Laws

Pharmaceutical companies and physicians are both subject to the Medicare/Medicaid Anti-Kickback Statute.[6] It prohibits false statements and representations made under Federal healthcare programs as well as the offer and solicitation or payment of remuneration (to include kickbacks, bribes, or rebates) in connection with services or items that are reimbursable by such programs.[7] Violators may be convicted of felonies or misdemeanors and are subject to heavy fines. Persons who submit false claims for reimbursement (such as the doctors in the TAP Pharmaceuticals case who were requesting reimbursement at the average wholesale price for Lupron when they had received discounted rates and free samples) also violate the False Claims Act.[8]

IV. OIG Guidelines

Guidelines for Individual and Small Group Physician Practices. OIG's model compliance plan for individual and small group physician practices highlights arrangements with pharmaceutical manufacturers and vendors as "areas of potential concern."[9] The OIG recommended that a physician practice's written standards and procedures include as a risk factor "soliciting, accepting or offering any gift or gratuity of more than nominal value to or from those who may benefit from a physician practice's referral of federal health care program business."[10] In footnoting this risk factor, OIG recommended that physician practices "establish clear standards and procedures governing gift-giving because such exchanges may be viewed as inducements to influence business decisions."[11] Therefore, as early as fall 2000, the OIG focused physician practice attention upon gifts and other financial relationships with pharmaceutical manufacturers and vendors as a risk factor and area of concern. Unfortunately, this guidance was not very specific regarding details of the practices that OIG considered to be problematic.

Guidelines for the Pharmaceutical Industry. Fortunately, more detailed advice regarding suspect relationships between pharmaceutical manufacturers or vendors and physicians is available to physicians from the OIG's *Compliance Program Guidance for Pharmaceutical Manufacturers*[12] (OIG Pharma. Guidelines). The OIG Pharma. Guidelines identify "three major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to establish payment; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples."[13] To deal with these risk areas, the OIG advocated that pharmaceutical manufacturers adopt a comprehensive compliance program, which includes written policies and procedures. Among these should be a code of conduct which expresses the company's expectations of its employees and summarizes the ethical and legal principles by which it will abide. Also, the written guidance should discuss the law relative to the three specific risk areas mentioned above, and how the pharmaceutical company will ensure that it complies with the law.

In regard to kickbacks and illegal remuneration, the compliance program should determine what practices would implicate the Anti-Kickback Statute as well as what practices are permitted, to include established safe harbors. If a safe harbor is not available, then the arrangement should be examined under the totality of the circumstances. Such a review would include at least five factors: (1) the nature of the parties' relationship; (2) how the remuneration is calculated; (3) the value of the remuneration; (4) whether the remuneration is governed by a federal (or state) program; and (5) whether the arrangement creates a conflict of interest for either party. This mechanism should be used to examine relationships between physicians and marketing agents, considering whether educational grants, research funding, or any other payments or subsidies may implicate the statute. Companies should scrutinize formulary support, the composition of formulary committees, and any payments thereunder. With regard to average wholesale prices, the focus should be on the potential for marketing considerations to influence pricing and reporting of costs. Specifically, sales representatives should avoid the TAP Pharmaceuticals practice of marketing the spread to physicians as a means of increasing prescriptions. Even though an

arrangement falls outside a safe harbor, it will likely not be a compliance risk if it does not: (i) increase costs or promote the over or improper utilization of federal and state healthcare programs; (ii) improperly steer patients or impact quality of care; and (iii) is not intended to cause or compensate referrals. Physicians and their legal counsel should consider this guidance whenever assessing existing or potential relationships with pharmaceutical manufacturers or vendors and their sales agents.

V. Physician Self-Regulation

In the 1990's, reacting to perceived abuses, the American Medical Association (AMA) published *Guidelines on Gifts to Physicians from Industry*. The guidelines have now been codified in the AMA's Code of Medical Ethics at Council on Ethical and Judicial Affairs (CEJA) Ethical Opinion 8.061.[14] This self-regulatory policy attempts to ensure that interactions between pharmaceutical company representatives and the physicians who are most likely subject to their influence remain above board and provide social benefit. Following its guidance will not substitute for applying the Anti-Kickback Statute, safe harbor regulations, court decisions, and OIG guidance to the facts and circumstances, but conformity with its requirements may substantially improve the likelihood of legal compliance for those arrangements to which a safe harbor does not apply.

Opinion 8.061 established seven guidelines. First, gifts should not be of "substantial value" and should primarily entail benefits to patients. For example, textbooks and modest meals are deemed permissible so long as they provide educational value, but cash payments are prohibited. Drug samples may be accepted, and can even be distributed to family members or used personally by physicians, as long as such use does not impact their availability to patients. Second, individual gifts of nominal value, such as paper and notepads that relate to the physician's work, are acceptable. Third, CEJA defined "legitimate" conferences and meetings as those where gatherings would be primarily dedicated to promoting objective educational or scientific activities and being centered on an educational presentation. Additionally, CEJA stated that the main purpose of the conference/meeting should be to further the attendees' knowledge on the subject. Finally, appropriate disclosures of financial support and conflicts of interest should be made.

Fourth, subsidies that underwrite costs of continuing education conferences and professional meetings are permissible, as they contribute to the improvement of patient care. However, subsidies should not be given directly to attendees, but rather to the sponsor of the conference (who would nonetheless have the discretion to use the subsidy to defray registration fees). Also, outside payments made directly to physicians, although they may serve the same purpose of reducing conference fees, are not permitted. Fifth, industry participants should not directly subsidize the cost of conference attendance by physicians, regardless of whether such payments are made for travel, lodging, or other expenses, nor should industry compensate physicians for time spent attending a conference. Hospitality events at a conference may be subsidized by industry companies, provided that such events are limited to modest meals and social events that serve an educational purpose and further the welfare of the public. Faculty and consultants who perform genuine services at a conference or meeting are allowed to accept honoraria and be reimbursed for the cost of travel, meals, and lodging. However, those who provide "token" consulting or advisory services are not justified in accepting compensation or reimbursement.

Sixth, medical students, residents, and fellows are allowed to receive scholarship and special funds to attend certain educational conferences, provided that the selection of students to receive the funds is made by the academic or training institution. In general, such scholarships and grants should be limited to funding attendance at major meetings of national, regional, or specialized organizations for scientific, educational, or policy-determining purposes. Seventh, gifts that come with "strings attached" should not be accepted. Because such gifts are inextricably tied to the physician's prescribing practices, they are inappropriate. Finally, while industry companies may underwrite the costs of meetings and conferences, they should not have control over the content, materials, or speakers—such discretion should remain with the organizers.

In response to numerous questions from physicians and others, CEJA issued an addendum (Addendum II) to opinion 8.061 in 2001.[15] The addendum amplified the previous guidelines and responded to specific questions. Speaker dinners, which are a popular education mechanism for pharmaceutical companies, were deemed permissible, so long as they are modest in nature. The addendum did not state a dollar limitation for meals, but stated that textbooks and other gifts that primarily benefit patients are permissible if their open market value is in the $100 range. Additionally, speaker dinners cannot merely be a platform for an industry representative to deliver a sales pitch, but rather must include an educational component delivered by an authoritative speaker.

Meals and food provided in the office or hospital environment, for the convenience of the physician, are also permissible, but should be of nominal value, and should include an opportunity for the sales representative to discuss the product with the physician (i.e., no drive-bys or drop-offs). Gift certificates may be provided to physicians, so long as they are not substantial in value or so frequent as to be substantial when viewed collectively, and may only be redeemed for items that benefit patient welfare.

Much of the new guidance was aimed at addressing industry-provided travel expenses and honoraria for physicians. The addendum stated that travel expenses may be paid when trips have a bona fide research purpose, and discussions are focused on clinical develop-

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ments and research results. When a physician provides genuine services, they may receive reasonable compensation in addition to travel expenses. Therefore, physicians acting in the role of faculty or participating in an appropriate focus group are entitled to reasonable compensation. Merely participating in an interactive exchange, or attending meetings, is not sufficient to warrant payment of compensation or reimbursement of travel expenses.

In amplifying guideline six, CEJA confirmed that all subsidized travel expenses for residents, students, and fellows should be made to the appropriate academic department, and not to the attendee. CEJA said the intent of permitting attendance scholarships was to ensure that financial hardships did not prevent students from attending major conferences and educational gatherings, excluding those designed specifically for students. Finally, CEJA confirmed that guideline seven was intended to complement the Anti-Kickback Statute and preclude preferred treatment and special favors for top prescribers, stating that there can be no link between prescribing or referring patterns and gifts.

VI. Pharmaceutical Industry Self Regulation

Physicians and their counsel may obtain further guidance from the voluntary *PhRMA Code on Interactions with Healthcare Professionals*[16] (PhRMA Code). The PhRMA Code mirrors the OIG Pharma. Guidelines. However, the PhRMA Code adopts a slightly different approach, as it is intended to address the day-to-day conduct of pharmaceutical representatives. Therefore, the PhRMA Code is generally more responsive to particular situations and industry practices, and provides clear-cut yes and no answers. Most pharmaceutical companies have adopted the PhRMA Code into a working manual or policy for their sales representatives. Continuous training and education in this area has become the industry norm.

While not aimed directly at physicians, the PhRMA Code provides the framework from which the pharmaceutical industry should be working. Therefore, doctors who know the PhRMA Code, and conform their dealings with manufacturers to its guidelines, reduce their risk of violating federal and state anti-kickback laws or violating the AMA Code of Ethics. The PhRMA Code is helpful in resolving specific questions that may not be addressed by the law, regulations, or OIG guidance.

VII. The Enforcer's Perspective

As evidenced by the TAP Pharmaceuticals and Pfizer prosecutions, as well as the 2005 DHHS OIG Work Plan, the government continues to aggressively target physicians and pharmaceutical manufacturers who abuse the laws. In particular, the government is looking to prosecute those who violate the Anti-Kickback Statute and False Claims Act. The whistleblower windfall created by qui tam actions is a powerful incentive that continues to assist the government in its efforts.[17]

In Advisory Opinion No. 04-03, the OIG stated that a marketing company program that paid physicians to complete pharmaceutical surveys would potentially violate the Anti-Kickback Statute. However, the OIG stated that it would not impose sanctions on the marketing company. Under the plan, physicians received a one dollar check on which the survey was printed, and upon completing the survey and endorsing the check, the physicians had the option to cash the check themselves or donate the dollar to a charity of their choice. Because the maximum amount of remuneration any physician would receive under the plan was only twelve dollars, the OIG determined that the risk that the remuneration would influence fraudulent or abusive practices was sufficiently low that administrative sanctions were not appropriate.

Despite the OIG stating that it would not pursue this arrangement, the tenor of the opinion clearly suggests that other arrangements will not receive such lenient treatment. "Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on *both* sides of an impermissible 'kickback' transaction. For purposes of the anti-kickback statute, 'remuneration' includes the transfer of *anything* of value, directly or indirectly, overtly or covertly, in cash or in kind."[18] The OIG interprets the statute to implicate "any arrangement where *one* purpose of the remuneration [is] to obtain money for the referral of services or to induce further referrals.[19]

Thus, physicians and physicians' counsel, be forewarned. The government is watching. Examine and re-examine physician arrangements and relationships with pharmaceutical manufacturers or vendors and their sales agents, be they speaking, research, consultation, gifts or other items. Read and heed the guidelines, know and live the law, and if in doubt, err on the side of caution!

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Endnotes

1 *See* Department of Justice Press Release dated October 3, 2001 available at www.usdoj.gov/opa/pr/2001/October/513civ.htm, last visited Nov. 22, 2004.

2 *See* Ray Moynihan, *Who Pays for the Pizza? Redefining the Relationships Between Doctors and Drug Companies*, 326 BMJ 1189 (2003), available at www.bmj.com. *See also*, "No Free Lunch: Just Say No to Drug Reps" website at www.nofreelunch.org.

3 *DHHS/OIG Fiscal Year 2005 Work Plan – Centers for Medicare & Medicaid Services* at 44.

4 *Id.* at 44-45.

5 *Id.* at 7.

6 *See* 42 U.S.C. §§ 1320a-7 *et seq.*

7 42 U.S.C. § 1320a-7b(a) & (b).

8 31 U.S.C. §§ 3729 *et seq.*

9 65 Fed.l Reg. 59434 at 59440 (10/5/00).

[10] *Id.* at 59441.

[11] *Id.* at 59441, Footnote 33.

[12] Issued in April 2003. Located at 68 Fed. Reg. 23731-43 (May 5, 2003), available at http://oig.hhs.gov.

[13] 68 Fed. Reg. 23732 (May 5, 2003).

[14] Available at www.ama-assn.org/ama/pub/category/print/4001.html.

[15] This addendum was first published in *The Food and Drug Law Journal*, vol. 56, issue 1. It is available at www.fdli.org.

[16] Available at the Pharmaceutical Research and Manufacturers of America website, www.phrma.org.

[17] As an example, David Franklin received over $26 million for his part in uncovering the abuses at Pfizer.

[18] DHHS OIG Advisory Opinion No. 04-03 at p. 4 (emphasis added).

[19] *Id.* (citing *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989) and *United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985) (emphasis in original).

Deciphering the OIG 2005 Work Plan

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Each fall the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) issues its Work Plan. Similar to a situation in which a police department discloses the sites of its speed traps in advance, the Work Plan discusses the subjects the OIG plans to target in the upcoming year.

The Work Plan "briefly describes the various project areas" that the OIG perceives "as critical to the mission" of DHHS and that "best identify vulnerabilities" at the agency.[1] The OIG creates the list after comprehensive financial and performance audits identify systemic weaknesses that give rise to fraud, waste, and abuse.[2]

The purpose of this article is to explain the compliance issues for a few of the new target areas in the Work Plan sections that apply to physician practices. It also compares the 2005 topic list to lists from previous years to provide insight into what the OIG identifies as its top enforcement priorities over time.

Although the OIG's audits often retrospectively target billing that was done before the Work Plan is published each year, attorneys who represent physicians and other providers can use the Work Plan prophylactically, particularly because many topics are carried over from year to year. Attorneys can incorporate the Work Plan subjects into their clients' tailored and updated compliance plans and audit initiatives. Instead of picking a compliance topic out of the blue, attorneys knowledgeable with the Work Plan choose subjects that the OIG states it is interested in, which may be more effective for clients who generally lack unlimited resources for compliance initiatives. In addition, the Work Plan is a useful tool in prioritizing existing compliance audit efforts.

As pressure grows in the industry to create more substantial and aggressive compliance programs, tailoring programs to the Work Plan provides a good marker against which to measure the substance and scope of the compliance program.

I. The 2005 Work Plan

The 2005 Work Plan targets 15 topics applicable to physicians who participate in Medicare.[3] The most interesting aspect of the 2005 Work Plan may be what is not new. Although there is typically some topic carry over from year to year, six of the 2005 Work Plan topics for physician compliance also appeared in the 2004 Work Plan. They include:

- coding of evaluation and management services[4]
- use of modifier -25
- use of modifiers with national correct coding initiative edits
- "long distance" physician claims
- ordering physicians excluded from Medicare
- care plan oversight[5]

Physician practices that tailor their compliance plans and audit initiatives each year based on the annual Work Plan should already be familiar with and have compliance procedures in place for these topics. If not, physician practices should take this opportunity to review these topics, as clearly the OIG's interest in them has not changed.

Also of interest is the fact that two overlapping topics that have been in the Work Plans for years—incident to services and non-physician practitioners—are gone from the 2005 Work Plan. Incident to and non-physician practitioner matters have made the list in some form since 2001. Also on the 2004 Work Plan but not included in 2005 were consultations, ESRD monthly capitation payment RVUs, place-of-service errors, billing for diagnostic tests, and radiation therapy services.

The nine new 2005 Work Plan subjects are:

- billing service companies
- Medicare payments to VA physicians
- wound care services
- physician services at skilled nursing facilities
- physician pathology services
- cardiography and echocardiography services
- physical and occupational therapy services
- Part B mental health services
- provider-based entities

The Work Plan only briefly identifies the topics. For example, under the "billing service companies" topic, the Work Plan states only: "We will identify and review the relationships among billing companies and the physicians and other Medicare providers who use their services. We will also identify the various types of arrangements physicians and other Medicare providers have with billing services and determine the impact of these arrangements on the physicians' billings." The Work Plan does not describe what exactly is suspect about the relationships nor does it describe how providers can remedy the suspect relationships. However, the OIG has been concerned in the past with "optimization" agreements, under which third-party billing companies review a provider's claims and look for services that were underbilled, in exchange for a percentage of the increased reimbursement. Such arrangements frequently resulted in claims the OIG viewed as potentially fraudulent, in part due to the economic incentives of the third-party billing companies. The OIG may be targeting these arrangements to find other inappropriate economic incentives.

Some of the other 2005 topic explanations demonstrate that financial issues frequently drive the topic choice. For example, the "care plan oversight" topic explanation states that "reimbursement for care plan oversight increased from $15 million in 2000 to $41 million in 2001. We will assess whether these services were provided in accordance with Medicare regulations."

The Work Plan does not, however, outline any specific concerns or compliance issues with those services. The remainder

of this article will explain a few of the topics in greater depth than the brief description in the Work Plan and make some educated guesses at what exactly the OIG may be targeting.

II. Wound Care Services

The OIG will look at billing for skin debridement services. Debridement is the process of removing non-living tissue from pressure ulcers, burns, and other wounds. When a physician performs debridement, the physician intends to remove all foreign/dead material, reduce the number of bacteria in the wound, and leave behind the viable tissue in order to promote healing.[6]

The Work Plan states that the OIG will determine whether claims for wound care services were medically necessary and billed in accordance with Medicare requirements.[7] Medicare-allowed amounts for certain wound care services billed by physicians increased from approximately $98 million in 1998 to $147 million in 2002, according to the Work Plan. The OIG states that it will also "examine the adequacy of controls to prevent inappropriate payments for wound care services."

The issues that the OIG is probably concerned with are: (1) whether wound debridement was truly provided or whether it was a simple cleaning, (2) if debridement was provided, was it medically necessary, and (3) whether a physician or non-physician practitioner provided the care (as certain codes for debridement are physician-only codes).

The OIG may also look at the frequency of the billing for wound care to see if the patient was benefiting from the debridement and there was progress toward healing. Physicians should document in the medical record the need for the debridement, and possibly include photographs. Also, the physician-only debridement codes (11040-11044) should not be used to describe the debridement of burn wounds.[8]

Another issue may be billing for multiple wounds. If there is more than one wound, certain debridement codes can only be billed once, but the 11040 series of codes can be billed for each wound debrided provided the services meet the "separate site" requirement. When reporting debridement of more than one site, the physician reports the secondary code (i.e., the second code listed) with a modifier appended, to indicate that different areas were given attention.[9]

III. Physician Pathology Services

The OIG states in the 2005 Work Plan that it will focus on "pathology services performed in physicians' offices."[10] It defines pathology services as the examination of cells or tissue samples by a physician who prepares a report of his findings. The Work Plan states that Medicare pays over $1 billion annually to physicians for pathology services. It states that the OIG "will identify and review the relationships between physicians who furnish pathology services in their offices and outside pathology companies."

While the OIG does not explain what its specific concerns are, one issue the OIG may be targeting is that of "swapping," which is the term used to describe the suspect deal or discount a pathology laboratory offers a physician practice in order to obtain its pathology business. This is less a billing issue and more of a kickback or illegal pricing issue. In a typical suspect arrangement a pathologist bills the private pay business to the practice (so that the practice can bill it to private payer and self-pay patients at a mark-up) but bills Medicare/Medicaid business directly to the programs. The OIG may be reviewing whether these kinds of discounts on private pay business are an inappropriate inducement for the referral of the Medicare/Medicaid business, which generally must be billed by the performing laboratory.

IV. Cardiography and Echocardiography Services

The OIG will examine whether physicians billed properly for the professional and technical components of cardiography and echocardiography.[11] The Work Plan states that "when a physician performs the interpretation separately, the modifier 26 should be used to bill Medicare for professional services."

Cardiography and echocardiography are two of many services for which the CPT codes reflect both technical and professional components. If the physician does the interpretation using hospital-owned equipment or space, the physician can legally bill for only the professional component. Hospital billing rules require hospitals to bundle facility services together, and do not generally allow physicians to bill for technical services provided at the hospital. The rationale in requiring use of the appropriate modifier to reflect that only the professional component was provided is that Medicare should not include in its reimbursement to the physician any amount which relates to the performance of the technical component in a hospital setting. Accordingly, if the appropriate modifier is not used, Medicare essentially pays twice for the same technical component, once to the hospital and once to the interpreting physician. If the physician is providing only a professional interpretation, the physician should use the -26 modifier. That modifier signals to the carrier to pay for the professional interpretation only. Physicians may generally bill for the global service if the service is provided in space owned or leased by the physician, with equipment likewise owned or leased by the physician.

V. Physical and Occupational Therapy Services

The Work Plan states briefly that the OIG will review Medicare claims for therapy services provided by physical and occupational therapists to determine whether the services were reasonable and medically necessary, adequately documented, and certified by physician certification statements.

Under the Medicare coverage rules, physical therapy and occupational therapy services are not generally considered to be medically necessary unless there is an expectation that the patient will improve significantly in a reasonable amount of time. Certain limited services provided to establish a maintenance

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program may also be covered. To document medical necessity properly, physicians should make sure plans of care are included in the medical record, and that the services provided are documented in the record and linked to the plan of care.

The physician certification statements are approvals by the physician of the plan of care. The initial certification must state that a written plan for furnishing such services is or was established by the physician, physical therapist, occupational therapist or speech pathologist, and is periodically reviewed by the physician or non-physician practitioner. The certification must state the services were furnished while the patient was under the care of a physician or non-physician practitioner, and the services are or were reasonable and necessary to the treatment of the patient's condition.

The physician must periodically renew the certification. If a therapy service continues more than 60 days, the medical record must indicate that a physician or non-physician practitioner has seen the patient within 60 days after the therapy began and every 30 days past the 60th day. If the requirement is not met, the therapy services are not covered.[12] The OIG will likely be reviewing whether these medical necessity and physician certification requirements which are necessary for coverage by the Medicare program are being met.

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Endnotes

1 2005 Work Plan, page 1, available at http://oig.hhs.gov/publications/workplan.html.

2 *Id.*

3 2005 Work Plan, page 10.

4 Evaluation and management services have been a Work Plan target subject each year since 2001.

5 Previous years' Work Plans are also available at http://oig.hhs.gov/publications/workplan.html.

6 CPT Assistant, May 96:6.

7 Work Plan, page 12.

8 CPT Assistant, August 97:6.

9 CPT Assistant, February 97:7.

10 Work Plan, page 11.

11 *Id.*

12 Pub. 100-2, §§220.2, 220.3.1, 220.3.3, and 220.3.4.

Unanswered Questions in Stark Law Indirect Compensation Rules

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I. Introduction

Entities that provide Medicare designated health services[1] (DHS) and physicians who refer such services are both required to comply with the Stark Law.[2] The Stark Law prohibits a physician from referring Medicare patients for DHS to an entity with which the physician (or an immediate family member) has a financial relationship unless an exception applies. The entity providing the DHS is prohibited from billing for any service so referred.

The Stark Law Phase II regulations, which became effective July 26, 2004 (Phase II Regulations), and the discussion contained in the preamble to those regulations (Preamble) provide inconsistent guidance on how to determine whether an exception applies when a DHS-providing entity contracts with a group practice rather than with an individual physician or solo physician professional corporation (PC). Before explaining the inconsistency, an explanation of how the Stark Law and Phase II Regulations categorize financial arrangements as direct or indirect may be helpful.

II. Types of Financial Relationships

For Stark Law purposes, a financial relationship can be either an ownership/investment interest or a compensation relationship. Each type of financial relationship can be either direct or indirect.

A direct financial relationship is one that is between the physician and the DHS-providing entity with no intervening persons or entities. For example, a physician's ownership of an interest in a group practice is a direct ownership/investment interest in the practice, and a physician's employment by a group practice is a direct compensation relationship with the practice.

The indirect ownership/investment interest is a straightforward concept. In a chain of financial relationships, ownership in the entity at the end of the chain is attributed to the physician at the beginning of the chain notwithstanding the presence of intervening entities. Thus, for example, if Dr. A owns an interest in Corporation X, which in turn owns an interest in Partnership Y, Dr. A will have an indirect ownership/investment interest in Partnership Y. However, ownership is not attributed "upstream," and so if Dr. A and Hospital B own interests in a joint venture, that does not result in Dr. A having an indirect ownership/investment interest in Hospital B.

Determining whether a set of financial relationships results in an indirect compensation arrangement for Stark Law purposes is more complicated. The Phase II Regulations establish a three-part test for determining the existence of an indirect compensation arrangement:

Indirect compensation arrangement. An indirect compensation arrangement exists if —

(a) An unbroken chain of any number of persons or entities (but not fewer than one) that share financial relationships exists between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS; that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link; and

(b) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under § 411.354(d)(2)[3] or (d)(3).[4] If the direct financial relationship between the physician (or immediate family member) and a person or entity in the chain is an ownership or investment interest, the determination of whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest in the chain to the referring physician (or immediate family member). For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph; and

(c) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.[5]

III. Indirect and Direct Compensation Arrangement Exceptions: the Inconsistency

In the Interim Final Rule and its preamble, the Centers for Medicare and Medicaid Services (CMS) make statements that are inconsistent and irreconcilable as they apply to certain types of indirect compensation arrangements. As explained below, the Preamble states that indirect compensation arrangements are to be evaluated based on whether they meet the requirements of the regulatory indirect compensation arrangement exception[6] and not based on whether exceptions for direct compensation arrangements and/or ownership/investment relationships apply to any intervening relationships.

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However, a number of Stark Law exceptions by their terms apply to arrangements with physician group practices, which is relevant to the Stark Law analysis only if the exception applies to referring physicians who have financial relationships with the group practice (or who have immediate family members with such relationships).

A. Preamble

The Preamble discussion indicating that only the indirect compensation exception can be relied on to except an indirect financial arrangement reads as follows:

> *Comment:* . . . Several commenters believe that there should be no indirect compensation arrangement if any financial relationship in the chain qualifies for an exception. One commenter pointed out that under section 1877(a)(2) of the Act, the definition of "financial relationship" excludes any financial relationship that fits in an exception. Thus, according to this commenter, the inclusion of an excepted financial relationship in a chain of financial relationships necessarily "breaks" the chain and precludes an indirect compensation arrangement. The commenter explained further that this result would make the application of the indirect compensation rules easier for DHS entities, especially hospitals, that have arrangements with group practices that employ, or contract with, referring physicians using compensation arrangements that fit in the employment, personal services contracts, or fair market value exceptions. Finally, the commenter suggested that, at a minimum, there should be no indirect financial relationship if every link in the chain qualifies for an exception.
>
> *Response:* . . . [T]he reference in the definition of "indirect compensation arrangement" to an unbroken chain of "financial relationships" as defined in § 411.354(a) includes both excepted and unexcepted relationships. A direct financial relationship can form a link in a chain of financial arrangements that creates an indirect compensation arrangement, even if the direct financial relationship qualifies for an exception. *While it is very unlikely, we believe that a chain consisting entirely of excepted financial relationships could theoretically create an indirect compensation arrangement, if the remuneration paid to the referring physician is not fair market value or varies with, or otherwise takes into account, the volume or value of referrals or other business generated for the DHS entity by the referring physician.* A more likely scenario is that the chain would either [sic] involve fair market value compensation that would qualify the relationship under the indirect compensation arrangement exception. We address the special issue of contracts with group practices in a subsequent response below. . . .
>
> *Comment:* A number of commenters expressed the view that an indirect compensation arrangement should be excepted if any link in the chain fits in one of the exceptions for direct compensation arrangements. This issue was raised by group practices that contract to provide services to hospitals (or other DHS entities) or to lease space or equipment from DHS entities. *For example, in the case of a services agreement between a hospital and a group practice, an indirect compensation arrangement is created between the hospital and the contracting group practice's employee or investor physicians (that is, the referring physicians). Instead of looking to the indirect compensation exception in such circumstances, commenters proposed that the test be whether the compensation arrangement between the hospital and the group practice fits in a direct compensation exception.* Commenters suggested that we use a similar rule for other indirect compensation arrangements involving referring physicians who are members of group practices, where the link in the chain closest to the referring physician is his or her compensation arrangement with his or her group practice. Commenters requested comparable relief with respect to physician-owned PCs. In the commenter's view, the fact that a physician practices through a wholly-owned PC should not convert a direct financial relationship with a DHS entity into an indirect relationship (that is, physician-PC-DHS entity).
>
> *Response: We do not agree that an indirect compensation arrangement should be excepted if any link in the chain complies with a direct compensation exception.* As we explained in the Phase I preamble (66 FR 867), we are concerned that, in some situations, such a test would permit a middle entity to redirect compensation to referring physicians based upon the volume or value of referrals or other business generated by the physicians to the DHS entity (which is not the middle entity).
>
> We recognize that it is not necessary to treat a referring physician as separate from his or her wholly-owned PC. We have revised the definition of referring physician in § 411.351 to reflect this clarification.
>
> By way of example, under the Phase I regulations, if a hospital contracted with a referring physician's PC for the provision of services, the hospital would potentially have an indirect compensation arrangement with the referring physician for which the only available exception would be the indirect compensation arrangements exception. Under the revised regulations, the contract would create a direct compensation arrangement between the hospital and the referring physician.
>
> We believe the revised regulations should make it simpler for physicians and others to evaluate their financial relationships and the application of exceptions under section 1877 of the Act.
>
> *We are not making any changes to the Phase I rule with respect to the issue of indirect compensation arrangements that are created when a group practice*

is an intervening entity in the chain between the DHS entity and referring physicians who are members of the group (for example, a hospital contracts with a group practice for services). The commenters' proposal that the regulations permit physicians to stand in the shoes of their group practices, thereby converting indirect arrangements to direct arrangements, is inconsistent with the compensation exceptions as drafted. We believe that the knowledge standard in the indirect compensation arrangements definition and exception adequately protects DHS entities. We solicit comments on this issue.[7]

B. The Phase II Regulations.

Despite CMS' apparent position in the Preamble that the personal services exception cannot apply where the agreement is with a group practice, the language of the Phase II Regulations supports the position that the personal services exception can apply in that setting. The personal services arrangement exception excepts "[r]emuneration from an entity under an arrangement or multiple arrangements to a physician, an immediate family member of the physician, *or to a group practice*, including remuneration for specific physician services furnished to a nonprofit blood center," provided specified conditions are met. Similarly, the "fair market value compensation" exception applies to "Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) *or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352)* for the provision of items or services by the physician (or an immediate family member) *or group of physicians* to the entity," provided that specific conditions are met.[8] The "group practice arrangements with a hospital" exception by its terms applies *only* to an arrangement with a group practice: the exception applies to "[a]n arrangement between a hospital *and a group practice* under which DHS are furnished by the group but are billed by the hospital," provided specified conditions are met.[9] This is consistent with the statutory language for this exception as well.[10]

In addition, the Preamble states that where a physician is recruited who joins an existing practice, the physician recruitment exception applies both to the relationship with the recruited physician and to the relationship with the existing practice.[11]

IV. Additional Guidance Needed

These inconsistencies are irreconcilable, and therefore additional guidance is necessary. Specifically, CMS should clarify:

(1) Where the statute, regulations, or preamble contemplates that an exception can be applied to an intervening physician group, as is the case with the personal services arrangement, fair market value, "group practice arrangements with a hospital" and physician recruitment exceptions, does a Stark Law exception apply to the indirect relationship between a physician owner or employee of that group and a DHS-providing entity contracting with that group if the conditions of either the applicable direct exception or those of the indirect financial arrangement exception are satisfied? This would appear to be a reasonable position, but it is contradicted by the Preamble discussion quoted above.

(2) If the indirect compensation arrangement exception applies, is it ever necessary to meet the additional re-quirements of a direct exception? For example, the direct lease exception requires a one-year term; the indirect compensation exception does not. It would seem reasonable to take the position that additional direct exception requirements are mandatory only if the contract is with the individual physician, wholly owned PC, or immediate family member (the effect of this regulatory scheme is, of course, to create burdensome requirements on leases and other contractual arrangements with solo practitioners that do not apply to contracts with physician groups). However, the inconsistent and confusing treatment of indirect compensation arrangements described above may result in some reluctance to rely on this position and cause parties to structure arrangements to meet both the direct and indirect requirements.

The inconsistency explained above creates unnecessary confusion for physicians, group practices, and DHS providers in structuring their financial relationships. Further clarification from CMS would be helpful.

* The author wishes to thank Tonya W. Conley, Esquire, an associate with Kutak Rock LLP, for her assistance in the preparation of this article.

Endnotes

1 The "designated health services" are clinical laboratory services; physical therapy, occupational therapy, and speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 C.F.R. § 411.351.

2 42 U.S.C. § 1395nn.

3 42 C.F.R. § 411.354(d)(2) states that: Unit-based compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account "the volume or value of referrals" if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.

4 42 C.F.R. § 411.354(d)(3) states that: Unit-based compensation (including time-based or per unit of service-based compensation) will be deemed to not take into account "other business generated between the parties" so long as the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement

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in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which will not be considered "other business generated" by the referring physician).

[5] 42 C.F.R. § 411.354(c)(2).

[6] 42 C.F.R. § 411.357(p). The indirect compensation arrangement exception applies if all of the following conditions are satisfied:

(a) The compensation received by the referring physician (or immediate family member) . . . is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(b) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(c) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

[7] 69 Fed. Reg. 16054 at 16059-60 (emphasis added).

[8] 42 C.F.R. § 411.357(l) (emphasis added).

[9] 42 C.F.R. § 411.357(h) (emphasis added).

[10] 42 U.S.C. § 1395nn(e)(7).

[11] The Preamble states:

[T]he regulations provide that the exception will apply to remuneration provided by a hospital (or FQHC) to a physician indirectly through payments to another physician or physician practice, as long as [specified] conditions [are met]. . . .

The regulations similarly apply to payments made directly to a physician who joins a physician practice. . . .

This rule for pass-through hospital recruitment payments establishes an exception applicable to the compensation arrangement created between the hospital and the recruited physician (and between the hospital and the existing physician practice).

69 Fed. Reg. at 16053 at 16096-97.

Upcoming Teleconference

Legal Impediments to Physician Practice Revenue Diversification Efforts: Office Based Outpatient Surgical Services; Ambulatory Surgical Centers; Concierge Medicine; and Others

Tuesday, January 25, 2005

Sponsored by Physician Organizations Practice Group of the American Health Lawyers Association

This teleconference will address various concepts that physicians and their legal advisers are implementing as proposed solutions to the limitations on professional income, addressing such issues as:

- Review the difficulties that physicians are seeking to overcome by devising new service programs, within their professional license specialty parameters.
- The ASC organizational formats, the Anti-Kickback Statutory restraints, the ASC Safe Harbor, the IRS Joint Venture concerns (with for-profit equity and governance participants), and other issues and comments.
- The interest on the part of some physicians to promote the migration of O/P surgical procedures from the Hospital to their own Office Based Surgical Services Suites and the attempts by States, in response to Hospital lobbying efforts, to restore Hospital controls, to regulate and control these physician efforts by restrictive CON limits as well as other legislative or regulatory responses, i.e. (Connecticut Public Act 04-249 and the New Jersey Tax) as well as other State based limitations.
- The growing interest by a discrete number of physicians to break the lock-step Managed Care Organization (MCO) assembly-line mode of serving 3,000 or more MCO subscribers by reducing the physicians-patient complement to a manageable 600 or so by embracing the concept of Concierge Medicine or Boutique Personal Care programs as presented by various companies or administered by the physicians themselves.

Presenters:

Scott Becker, Esq., *McGuire Woods LLP, Chicago, IL*
Darin Engelhardt, Esq., *MDVIP, Inc., Boca Raton, FL*
Roy R. Harris, Jr., Esq., *Associate General Counsel, MDVIP, Inc., Boca Raton, FL*
Stephen E. Ronai, Esq., *Murtha Cullina LLP, New Haven, CT*
Michael F. Schaff, Esq., *Wilentz Goldman & Spitzer PA, Woodbridge, NJ*

Moderator:

Lisa D. Taylor, Esq., *St John & Wayne LLC, Newark, NJ*

The HIPAA Security Rule Creates New Compliance Challenges for Physician Practices

Elizabeth Warren, Esquire
Bass Berry & Sims PLC
Nashville, Tennessee

I. Introduction

Physicians still recovering from drafting and implementing policies, training staff, and negotiating business associate agreements in order to comply with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule[1] now must turn their attention to the HIPAA Security Rule.[2] Compliance with the Security Rule is required for most covered entities[3] by April 20, 2005.

The Security Rule applies to electronic protected health information (EPHI), which refers to individually identifiable health information that a covered entity creates, receives, maintains or transmits electronically. Covered entities must ensure the confidentiality, integrity, and availability of EPHI. Further, covered entities must protect against any reasonably anticipated threats or hazards to the security or integrity of EPHI. They must also protect against any reasonably anticipated non-permitted uses or disclosures of EPHI, and ensure that members of their workforces comply with the Security Rule.

This article briefly describes: (1) the flexible regulatory approach used in the Security Rule; (2) the three types of Security Rule safeguards; (3) the need for a risk analysis as the first step for compliance; and (4) the need to revise business associate agreements.

II. Flexibility, but Also Uncertainty

In drafting the Security Rule, the Centers for Medicare and Medicaid Services (CMS) took a goal oriented approach, rather than mandating specific security methods or procedures. CMS selected this approach to permit innovations in technology and to allow for differences in size and resources of covered entities. The downside of this approach is that covered entities lack a clear compliance checklist and will not have complete certainty that the security measures they adopt will be deemed compliant in hindsight in the event of a security breach.

The Security Rule contains implementation specifications, which are instructions on how to implement each standard of the Security Rule. These specifications consist of required and addressable specifications. Required specifications are mandatory and must be implemented. Addressable specifications are suggested methods of compliance that each covered entity must evaluate in light of the entity's risk analysis, risk mitigation strategies, existing security measures, and financial resources. If the covered entity determines that the specification is reasonable and appropriate, the entity must implement it. If the entity determines that the specification is not reasonable and appropriate, the covered entity must document this decision and implement any alternative the covered entity believes to be reasonable and appropriate. In recently issued guidance,[4] CMS emphasized that "addressable does not mean optional." Covered entities should consider, when documenting their decision to implement or not implement an addressable specification, that such documentation could be discoverable by private parties[5] pursuing claims based on alleged damages resulting from a security breach and likely will be requested by CMS when investigating potential Security Rule violations.

III. Three Types of Safeguards

The Security Rule contains three types of safeguards that covered entities must implement: administrative, physical, and technical safeguards. Administrative safeguards consist of administrative functions taken to select, implement, and maintain security measures to protect EPHI. Administrative safeguards include performing a risk analysis, naming a security official, and adding certain security items to business associate contracts.

Physical safeguards are steps taken to protect an entity's electronic information systems, equipment, and buildings from unauthorized access and from natural or environmental hazards. These safeguards include implementing controls that limit physical access to authorized personnel and taking steps to secure computer workstations.

Technical safeguards refer to the automated processes that are used to protect EPHI and control access to it. Electronic information systems must be structured so that only authorized persons or software programs are granted access. Use of encryption for electronic information sent over the Internet is not mandatory, but is an addressable specification and, therefore, must be implemented if reasonable and appropriate. Other technical safeguards include having mechanisms to audit and examine information system activity for improper access and having policies to protect information from improper alteration or destruction.

IV. Risk Analysis as the First Step for Compliance

Performing a risk analysis is a required specification under the Security Rule. Accordingly, covered entities must conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the security of EPHI maintained by the covered entity.[6] Performing a risk analysis will enable the covered entity to determine its flow of EPHI. For example, the analysis should identify where EPHI is stored, what software programs are used to handle EPHI, and what methods are being used to exchange EPHI. Once the covered entity has documented the flow of EPHI, the covered entity can: (1) evaluate the threats and vulnerabilities to its EPHI, (2) evaluate the levels of risk based on how critical the function, system, or information is to the covered entity, and (3) prioritize actions needed to mitigate identified threats and vulnerabilities based on its determination of risk. A well-performed risk analysis will help the covered entity create a roadmap for compliance with the other requirements of the Security Rule.

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V. More Business Associate Agreement Negotiations

Covered entities are already required to have business associate agreements in place under the Privacy Rule. The Security Rule requires covered entities to include additional elements in business associate agreements, if the business associate will transmit or maintain EPHI. Specifically, the agreements must require business associates to report all security incidents and to implement adequate security measures. Many entities that have already signed business associate agreements for purposes of the Privacy Rule will need to amend these agreements to add the items specified by the Security Rule.

VI. Conclusion

Physicians who have not already begun taking steps to comply with the Security Rule need to familiarize themselves with the requirements of the Security Rule, complete a risk analysis, and begin working on implementing the required safeguards as soon as possible. Depending on the size of the physician practice, the complexity of its information systems, and the sophistication of the practice's existing technical and security advisors and staff, the practice may need to engage a consultant, who is familiar with the Security Rule and security methodologies, to work with legal counsel to devise and implement a plan to address the Security Rule requirements.

Endnotes

[1] 45 C.F.R. Part 160 and Part 164, Subparts A and E, issued pursuant to HIPAA.

[2] 45 C.F.R. Part 160 and Part 164, Subparts A and C.

[3] The HIPAA Privacy Rule and Security Rule apply to covered entities, which consist of healthcare providers that engage in HIPAA standardized transactions electronically (most physicians), health plans, and healthcare clearinghouses. 45 C.F.R. § 160.102.

[4] CMS, "Security 101 for Covered Entities," *HIPAA Security Series*, Nov. 2004.

[5] The Security Rule does not create a private right of action, but individuals who believe that they have been harmed by a Security Rule violation may attempt to bring causes of action based on state law statutory and common law duties of privacy.

[6] 45 C.F.R. § 164.308(a).

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Physician Organizations