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New bill to give 'fair warning' about vague regs

Physician groups say Fair Warning Act could eliminate deliberate ambiguity of Stark II

A new bill introduced in Congress just days ago would prevent federal investigators from capitalizing on the confusion created by vaguely written laws like the Stark self-referral laws. The Regulatory Fair Warning Act of 1999, introduced by representative George Gekas (R-PA), would prohibit all federal agencies from imposing sanctions on anyone "for violating a rule if the agency finds that the rule failed to give the person fair warning of the conduct that the rule prohibits or requires." In other words, agencies like the Health Care Financing Administration would have to say what they mean in language a "reasonable person" could understand, says **Jim Harper**, JD, Gekas' general counsel and the author of the bill.

What's more, the bill would prevent courts from imposing civil or criminal penalties for the violation of any rule that failed to clearly state ("give fair warning of") the conduct it either prohibits or requires.

The problem, Harper says, is that the current legal structure of the nation's administrative laws "actually incentivizes vague regulations. The agencies actually preserve power by writing such regulations. They're simply following Supreme Court cases that give them the most credit if they don't come up with clear regulations at the outset."

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Documentation: What auditors are looking for

With HCFA and the Office of the Inspector General focusing more and more attention on whether prescribed services and treatments are medically necessary, accurate documentation of patient records has become crucial. Indeed, in its model compliance guidance for third-party billing companies, OIG ranked poor documentation at the top of its list of suspicious and questionable billing activities.

The problem is that "many physicians simply don't see the reason for wasting time writing down

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DOJ: Physicians to be next target in lab probe

Although the federal government's crackdown on clinical laboratories so far has focused mostly on the labs themselves, the second stage of the initiative probably will focus on the large number of physicians whom Justice Department investigators claim accepted kickbacks in exchange for referrals to those labs.

Indeed, physicians are an integral part of the spate of recent settlements between the DOJ and clinical labs over the issue of illegal kickbacks. **(See related story on the latest and potentially the largest settlement, p. 4.)** Even so, given the astronomical sums clinical labs are agreeing to pay, physicians may feel they've slipped below the government's radar on this one.

But that isn't the case, says **Michael Loucks**, JD, chief of the health care fraud unit at the U.S. Attorney's Office in Boston. Loucks is a key player in settlement talks with Lexington, MA-based lab company Fresenius Medical Care North America.

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Fair warning

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Although the bill isn't specific to health care, a number of physician groups and other health care organizations have mobilized in support of it. That isn't surprising, Harper says, considering that HCFA is among the worst offenders. "A lot of HCFA's so-called regulations aren't actually written down anywhere," he says. "So some members of the industry have been subject to suit for violating regulations that never actually existed on paper. The bill would protect providers in those kinds of situations."

Most important for physicians, however, is that the bill also would force HCFA to come clean about its Stark II self-referral regulations, says a spokesman for the Englewood, CO-based Medical Group Management Association, which is formally supporting the bill. "The ambiguous and complex nature of the [self-referral] regulations creates an unfair environment in which individuals do not understand the type of conduct that's prohibited under Stark," says the spokesman.

Because the Stark regulations are civil rather than criminal laws, prosecutors don't have to prove criminal intent to win a judgement against you. They only have to prove you made mistakes: "If you go through the hoops and don't meet one of the exceptions, then you are dead," says **Sally Barber**, JD, an attorney with Parker, Poe, Adams & Bernstein in Charlotte, NC.

The basic gist of the law is that physicians cannot refer patients to any entity in which they or their immediate family members have a financial interest for a designated health service for which Medicare or Medicaid may pay. Immediate family members include not just spouses and children but parents, grandparents, step-family, and in-laws. While the law's intent may seem straightforward, its specific provisions are anything but, critics complain.

Indeed, although the 100-plus pages of Stark II regulations were first published in the *Federal Register* more than a year ago (Jan. 9, 1998), HCFA still has not clarified some of the issues they raise. For example, one issue yet to be decided that could affect group practices is how "unified" the businesses have to be. Stark II has introduced a concept that you must have centralized decision making, pooling of expenses and revenues, and a distribution system that doesn't treat each office as its own entity, Barber says.

"If you have three offices that are all their own cost centers, then you may not qualify as a group practice," she says. "You would probably have to centralize and create a board for making decisions. If you have all three sites leased, then all the docs at all the offices should pay an equal share of the total of all the rents." **(For more help on Stark II, see "Understanding the maze of Stark II regulations," *Physician's Compliance Hotline*, Feb. 1, 1999, p. 1.)**

The regulations meant to clarify some of these issues were supposed to be ready in 1998, but the comment period was extended. Barber says the optimists predict they'll be ready this year, while the pessimists are betting on 2001.

Those regulations will include a reporting requirement for practices. "They don't have a form completed yet, but eventually, physicians will have to report all their financial arrangements," Barber says.

Those who still have questions can write or call HCFA eventually, Barber says. "But they aren't answering a whole lot of questions right now."

Meanwhile, the Gekas bill, though only just introduced, has already garnered the support of 42 different industry groups, and Harper contends that its prospects for passage in the 106th Congress are "very good." ■

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all the details of a diagnosis they have already worked out in their head and which they feel is right and makes perfect sense," says **Catherine Fischer**, CPA, a reimbursement policy advisor at Marshfield (WI) Clinic.

Indeed, HCFA auditors say it's not unusual for them to find no documentation in a patient's file to support what were probably a proper diagnosis and action taken by the doctor.

Here are a few red flags auditors look for to determine if they should dig deeper into a provider's files and past claims for suspicious activity:

♦ **Patient records that look alike.**

The fraud police want to be able to compare the records of different patients and find slight variations in how they are documented. Even allowing for whatever documentation procedures a practice uses, auditors expect documentation methods not to be exactly alike between any two or more records. "Using the same wording and checking off the same problem levels are the kind of things that catch an auditor's attention," says OIG spokesman **Ben St. John**.

♦ **Inconsistency between the chart and the evaluation and management guidelines.**

When the information contained in a patient's chart is not consistent with the related evaluation and management guidelines, this sends up another flare that gets the auditors' attention.

♦ **Mismatch between procedure code and setting.**

Are you coding for procedures normally done in a hospital while claiming an office visit?

♦ **Discrepancy between procedure codes and the diagnostic codes.**

Does the prescribed treatment match the diagnosis?

♦ **Spiked billing patterns.**

Are your billings abnormally high compared to the average for a particular code or medical service, or compared to other physicians in your specialty?

♦ **Incomplete or truncated diagnostic codes.**

This is one of the most common reasons for issuing a medical necessity denial. If it seems like you have been receiving an unusually high percentage of rejections for certain procedures, make sure your codes and computer systems are up to date. Also, take a close look at your "5th digit" coding patterns to ensure they are both up to date and as specific as possible when it comes to completing the patient's diagnostic profile.

The Chicago-based American Medical Association's Office of General Counsel has developed model physician compliance guidelines outlining the minimum standard each file should meet to properly document medical services that have been provided. Each patient encounter documented in the medical record should include:

- reason for the encounter;
- relevant medical history;
- findings of the physical exam;
- prior diagnostic test results;
- current assessment, clinical diagnosis, or impression;
- care plan;
- date;
- name and identity of any observers;
- rationale for ordering any additional diagnostic or ancillary services and tests that are inferred but not documented in the record;
- past and present diagnoses made accessible to treating and/or consulting physician;
- identification of appropriate health factors;
- patient's progress and response to treatment, any changes in treatment, and any revised diagnosis;
- CPT and ICD-9 codes reported along with appropriate documentation. ■

DOJ steps up its fraud enforcement efforts

The number of criminal health care fraud cases prosecuted by U.S. Attorney's Offices has more than tripled since 1993, according to a new study conducted by researchers at Syracuse (NY) University. In addition, in 1997 (the most recent year studied by the report), more than $1 billion was returned to the Medicare trust fund as a result of civil and criminal fines, judgments, and settlements.

Also in 1997, DOJ opened more than 1,400 criminal health care fraud cases, achieving a conviction rate of 87%. The percentage of convicted defendants who actually saw jail time was 54%. ■

Lab probe

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"The perception may be that the U.S. Attorney's Offices focus more on the payer [in kickback cases]," Loucks says. "But very often, the perceived bad guy can be the payee — the physician who receives the money in exchange for referral or service. That's because the physician is often seen as the one who has some control over where patients obtain a subsequent medical service, like a drug, a medical device, or a course of treatment that the physician can't provide."

Even so, Loucks admits that DOJ investigators don't bother investigating physicians unless someone's made a specific allegation against them, or unless investigators come across damaging evidence against a physician as part of a separate investigation.

For example, if the DOJ investigates a clinical laboratory, it may come across records suggesting a certain physician has received inducements in exchange for referrals. "In that circumstance, we'll investigate it, but we don't go looking unless we have an allegation, whether it be from the doctor's staff, the clinical laboratory's staff, or some competitor," Loucks says.

Another way DOJ investigators track down physician misconduct is examining medical sales reps' call reports, Loucks adds. "That can be a fruitful source of evidence," he says. Essentially, after sales people pay a call to a physician's office, possibly for the purpose of selling laboratory services or other supplies, they typically take notes on what transpired during the meeting.

"Salespeople generally don't have the ability on their own to give something to a physician; they don't have the budget," Loucks says. "So they have to get approval from somebody else. And it's surprising how often a paper trail is left." ■

Talks continue on possible record kickback settlement

Negotiations between the Department of Justice and Fresenius Medical Care North America of Lexington, MA, may lead to the largest criminal fine ever handed down in a health care fraud case, according to sources close to the case. That means it would top the $119 million fine paid by Needham, MA-based Damon Clinical Labs in 1996.

According to the U.S. Attorney's Office in Boston, a company bought by Fresenius in 1996 paid physicians as much as $20 million over a nine-year period in order to secure referrals.

The company Fresenius bought, National Medical Care Inc., was the market leader in kidney dialysis equipment. Fresenius also provides extensive laboratory services focused on end-stage renal disease, according to **Howard Bilow**, a Fresenius spokesman.

Court papers contain accounts of extravagant parties held for physicians, hunting trips arranged for physicians, and a consistent practice of giving physicians illegal cash rebates if they bought certain machines or testing products. The government also charges that physicians were actually put on National's payroll and provided with exorbitant salaries as medical directors at the company's dialysis clinics.

David C. Weber, a former vice president of sales at National, already has pled guilty to giving physicians between $10 million and $20 million in kickbacks in exchange for referrals. Weber has also agreed to testify on behalf of the government in the case against Fresenius.

Bilow points out that Weber "separated from the company" in 1993, long before Fresenius acquired it. He also stresses that none of the charges concern activities that took place after the acquisition.

Neither Bilow nor representatives at the U.S. Attorney's Office in Boston would say whether any physicians have yet been charged in the case. ■

AARP releases new fraud study

A new study conducted by the Washington, DC-based American Association of Retired Persons (AARP) claims that as many as 90% of Americans think health care fraud is on the rise, while nearly as many (80%) aren't aware of any attempt on the part of the government to fight the problem. AARP notes that another 72% believed health care fraud is so widespread that if abuse were eliminated, the Medicare program would remain solvent. ■