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DOJ ends controversial 'demand letter' campaign

In what may be the first major victory against the federal government's aggressive — and some say intimidating — use of the False Claims Act to bully hospitals into quick settlements, the Department of Justice has agreed to stop sending letters to hospitals demanding restitution for alleged billing fraud.

Justice's announcement to replace the demand letters with toned down "contact" letters came a week after a March 31 meeting between department officials and representatives of the Chicago-based American Hospital Association.

In that meeting, the AHA urged that Justice agree not to pursue false claims actions against hospitals when less than $100,000 is in dispute, and to temporarily suspend use of the False Claims Act. The DOJ refused both requests, and a department spokesperson vigorously denies that the DOJ has caved in to any demands or criticism leveled against it either by special interest groups like the AHA or members of Congress such as Rep. Bill McCollum (R-FL), who has co-authored a bill to water down the False Claims Act.

Even so, the decision to discontinue use of the demand letters comes only weeks after 46 Colorado hospitals were hit with written allegations about false billing practices. The letters they and other hospitals have already received typically contained a dollar amount and a demand that the hospital repay Medicare or face steep penalties.

*See **Demand**, page 3*

Medical societies take on OIG over PATH audits

With neither side showing signs of backing down, the legal battle between federal health care investigators and a coalition of major medical associations over the government's controversial Physicians at Teaching Hospitals (PATH) audit initiative is set to escalate a week from today.

On April 27 in Santa Ana, CA, oral arguments will begin in a lawsuit filed by the Chicago-based American Medical Association and other groups against the HHS Office of the Inspector General in an attempt to end the PATH initiative as it is currently being conducted. Meanwhile, the Greater New York Hospital Association, based in New York City, is only days away from filing a similar lawsuit against the federal government over pending PATH audits in New York State.

There are good reasons why the hospitals are digging in their heels. Only last month, the fourth PATH investigation was settled when the University of Pittsburgh School of Medicine

*See **PATH**, page 2*

OIG issues opinion on drug company kickbacks

In only its second advisory opinion of the year, the HHS Office of the Inspector General (OIG) has clarified whether certain discount pricing arrangements between pharmaceutical manufacturers and drug wholesalers violate the federal anti-kickback statute.

Essentially, the opinion gives drug companies more latitude in trading pricing discounts for marketing considerations.

The opinion is mildly surprising in that the OIG historically has expressed concern about such

*See **Kickbacks**, page 4*

INSIDE:

PATH

Continued from page 1

agreed to pay the government $17 million to avoid long and costly litigation over alleged violations of the False Claims Act. **(See related story on the settlement, below right.)**

Until the Pitt settlement was announced, some had hoped that federal investigators were backing away from the PATH initiative, which is designed, in part, to investigate teaching institutions at which physicians claim Medicare Part B reimbursement for services actually rendered by residents. **(See related story on how to avoid a PATH audit, page 3.)**

Last year, the Department of Health and Human Services revised its PATH policy, saying it would not prosecute institutions served by carriers that had provided inadequate guidance on PATH reimbursement rules. Because of that new policy, the department dropped 16 of 49 academic health centers from its investigation.

The AMA welcomed the PATH revisions but notes that after eliminating the 16 teaching institutions from its investigation, the government announced plans to add 20 or 30 more this year. Currently, 39 institutions are being targeted by PATH investigators, according to the OIG.

Five of those institutions are in New York State, where the Greater New York Hospital Association is filing a suit of its own against the government for its handling of the PATH initiative. Susan Waltman, JD, the association's general counsel, says the basis of the suit is the government's reliance on the clarity of documents provided to hospitals by local carriers.

"You can't have local carriers setting policy without the federal rule-making process," Waltman says. She adds that because the federal government's guidelines themselves are unclear, teaching hospitals are being investigated for things that have less to do with fraud than with misunderstandings over how claims are documented. "A great deal of this gets down to nothing more than documentation and whether a counter-signature is an acceptable means of demonstrating physician presence." Both suits come only a month after the most recent big-money PATH settlement in Pittsburgh.

The AMA's suit, filed in October 1997, also includes as plaintiffs the Washington, DC-based Association of American Medical Colleges (AAMC), as well as 13 academic organizations and 30 medical societies. ■

Pitt pays $17 million to settle PATH suit

In March the 18 clinical practice plans affiliated with the University of Pittsburgh School of Medicine agreed to pay the federal government $17 million to settle allegations that it defrauded Medicare and Medicaid with false claims between 1990 and 1996.

In a statement released shortly after the settlement, the institution maintained that the settlement had "nothing to do with the quality of services provided to patients, nor does it indicate fraudulent conduct." Administrators there stress that they chose to settle only in an effort to avoid "long and costly litigation."

The institution criticized the government for retrospectively applying billing standards set in 1996 to cases dating back as far as 1990. Pittsburgh is the fourth institution to settle a PATH investigation. Other institutions to settle include the University of Pennsylvania, Thomas Jefferson University Hospital, and the University of Virginia. ■

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Use these tips to prevent PATH audits

The requirements for billing Medicare for services supervised by teaching physicians are not as cut and dried as they seem. In an effort to help teaching institutions make sense of the federal government's requirements for billing Medicare for services supplied by teaching physicians, the Washington, DC-based American Society of Internal Medicine offers the following advice:

♦ **Medical records**. A patient's medical record must include documentation to substantiate the claim submitted. However, unless specifically requested, the teaching physician does not have to submit these records with the claim.

♦ **Modifiers.** Teaching physicians must use the -GC modifier with a claim to indicate that a resident was involved in the service provided. Otherwise, HCFA assumes it was provided exclusively by the physician and that no resident was involved.

♦ **E/M services.** Teaching physicians must perform — and document in the patient's record — the necessary work to bill for an evaluation and management service. However, they do not have to redocument all the information that the resident has already entered in the record.

Teaching physicians must review the system or systems relevant to the patient's current illness and document the major findings from the system review and exam. However, they do not need to perform a complete review of all systems or repeat documentation for the review of systems and past family and social history that the resident has already provided.

Teaching physicians must include summary notes of the key elements of the service (history of present illness, exam, and medical decision-making such as diagnosis and plan of care) in the patient's record. This combined documentation in the patient's medical record by the resident and teaching physician will be used to substantiate the level of services billed.

♦ **Ambulatory care exception.** There is an exception for ambulatory care entities that receive intermediary payments based in part on time spent by residents in patient care activities. These facilities also must provide acute care of undifferentiated problems or chronic care for ongoing problems, coordination of care, and comprehensive care that is not limited by organ system or diagnosis.

Under this exception, residents can bill for E/M services for levels one through three only. Any resident furnishing a service without a teaching physician present must have completed more than six months of an approved residency program. A teaching physician may supervise up to four residents at a time and must be immediately available to assume management responsibility for patients seen by residents in the ambulatory care facility.

♦ **Procedures.** The record for a minor procedure taking less than five minutes must document that the attending physician was physically present for the entire procedure. The record for a claim for other procedures must document that the attending physician was physically present for the key portion of the procedure.

♦ **Critical care services.** Claim records must document the physical presence of the teaching physician for the entire period indicated by the critical care code.

♦ **Signature and proxy stamps.** Signature stamps and electronic signatures are acceptable for noting who provided the service. Proxy stamps for covering physicians are also acceptable. ■

Demand

Continued from page 1

The less belligerent contact letters, on the other hand, will still state the DOJ's suspicions of billing fraud but will not include specific demands for financial restitution.

For the demand letters, the DOJ got billing information from Medicare carriers through the Health Care Financing Administration, then analyzed the information to detect irregular claims submissions patterns. The plan had been to hit all 50 states and all 4,700 hospitals in the Prospective Payment System, says Leo Reichert, JD, an attorney with the firm of Parker, Hudson, Rainer and Dobbs, LLP in Atlanta, and a former member of the U.S. Attorney's Office.

Reichert says the idea for the demand letter project started when the DOJ became involved in investigating 72-hour window violations a few years ago. "It was a new idea for these kinds of nationwide investigations," he says. "It was relatively inexpensive for the government to pursue

the claims, and the potential recoveries would be significant."

Indeed, the demand letters have been a cash cow for the federal government, according to the Department of Justice's own statistics. For example, in its 1997 annual report on health care fraud and abuse, the DOJ claimed that "a significant portion of the $1.087 billion collected [by the government in health care fraud cases] was the result of nationwide investigations into fraudulent billing practices of hospitals and independent laboratories" — two key targets of the demand letters. (In addition to hospitals charged with 72-hour window violations, independent laboratories also received letters as part of the government's lab unbundling project.)

One reason the letters were so successful, Reichert says, is that no one ever resisted them. "Not a single hospital in the 25 or 30 states they targeted fought them on it," he says. "Everyone kept rolling over and settling. The AHA was trying to find a hospital or hospitals to fight this aggressive use of the False Claims Act, but everyone was afraid to challenge them. The amount of money involved could become very significant if you fight, and the settlement ranges are fairly reasonable." ■

Kickbacks

Continued from page 1

arrangements in which marketing activities are bartered for a percentage of products sold. D, McCarty Thornton, chief counsel to the IG's office and author of the opinion, contends that such arrangements can, "in certain cases, encourage overutilization or the inappropriate steering of federal health care program business."

The opinion was written in response to a request from an unnamed pharmaceutical company.

According to the opinion, the company has proposed to enter into contracts with drug wholesalers for the purchase of "certain multi-source generic pharmaceuticals" at a fixed percentage price discount. In exchange for the discount, the wholesalers, whose customers include hospitals, pharmacies and other health care providers that serve federal beneficiaries, would provide "limited promotional support" for the drugs in question — in other words, marketing the drugs to their customers.

Under the company's proposed arrangement, the amount of the discount would be based on the amount of the wholesaler's contract product purchases minus returns, invoice adjustments and chargebacks, and multiplied by "a fixed percentage" not defined in the opinion.

At issue in all this is whether the exchange of discount for promotion and marketing constitutes an illegal kickback under either the Social Security Act (SSA) or the OIG's own civil monetary penalty provision for kickbacks. According to the SSA, payments cannot be made to induce referrals of business payable by a federal health care program. According to Thornton, the statute has been interpreted to cover any arrangement where one purpose of the payment was to "obtain money for the referral of services or to induce further referrals."

In analyzing the company's proposed arrangement, Thornton concluded that:

1. The arrangement is subject to the anti-kickback statute in that it does involve an exchange of remuneration (the discount) in exchange for marketing that could influence health care providers to purchase products.

2. Further, the arrangement isn't covered by the safe harbor governing price discounts. According to Thornton, the discount safe harbor only protects remuneration on a good or service received by a buyer that "submits a claim or request for payment for the good or service for which payments may be made in whole or in part under Medicare or a state health care program." Because the wholesalers won't be submitting claims to Medicare or Medicaid, the arrangement isn't covered.

3. Even so, the proposed arrangement isn't illegal because the discounts in question don't constitute "prohibited remuneration" under the anti-kickback statute. The reason, basically, is that even though the wholesalers won't be submitting claims to Medicare for the purchases, the Company's agreement to disclose information to the government "will insure that the discounts are properly reported and reflected in the Medicaid rebate."

Thornton notes that the opinion only applies to one specific case. It shouldn't be relied upon as a broad policy by entities involved in similar but not identical arrangements, and it isn't binding for any agency other than HHS. ■