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New HHS Inspector General lays out upcoming OIG agenda

Rehnquist cites administrative remedies, quality of care, and changes to CIAs

Health and Human Services Inspector General **Janet Rehnquist** laid out her blueprint for the Office of Inspector General's (OIG) anti-fraud initiatives last week. The result was a mixed bag for compliance officers.

On the one hand, Rehnquist promised expanded use of administrative remedies and systematic scrutiny of quality of care. But she also announced a streamlined civil settlement recovery process that may offer some relief as well as specific steps to improve the use of corporate integrity agreements (CIAs) and make them more cost-effective.

"I think you will see many positive changes," Rehnquist told attendees at a health care fraud conference in Washington, DC, cosponsored by the Philadelphia-based Health Care Compliance Association and the Washington, DC-based American Health Lawyers Association. She added that she has her own ideas about health care fraud enforcement, which primarily stem from her experience as an Assistant U.S. Attorney.

Rehnquist says her first objective is to streamline the civil recoveries process by improving communications and coordination among federal agencies as well as state and local law enforcement officials. She also plans to more effectively

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HIPAA emerges as top compliance issue

Sixty-two percent of survey respondents to the Philadelphia-based Health Care Compliance Association's (HCCA) Fourth Annual Profile of Health Care Compliance Officers report that compliance with the Health Care Portability and Accountability Act (HIPAA) is the biggest issue they face today.

In response to the question, "What specific goals do you hope to achieve in your compliance program in the next three years?" HIPAA compliance also was cited most frequently (84%), closely followed by monitoring/auditing (83%), education/training (76%), and conducting program

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OIG workplan zeroes in on inappropriate discharge

The Health and Human Services' (HHS) Office of Inspector General (OIG) Workplan for FY 2002 strongly suggests that the OIG's next emphasis is going to be on discharge patterns such as inappropriate discharge and readmissions, and inappropriate transfers from acute care settings to other units.

Health care attorney **Craig Holden** of Ober Kaler in Baltimore predicts these areas may well represent the next national projects. He notes that all of the existing national enforcement initiatives, such as pneumonia upcoding and the Physicians at Teaching Hospital (PATH) investigation are in their final stages. Several states still are working on laboratory cases, and there are several ongoing PATH settlements, he adds, but those investigations are winding down.

Robert Homchick, a partner with Davis Wright in Seattle, agrees that the area of transfers and dis-

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OIG agenda

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employ the civil monetary penalties (CMP) law and exclusion authorities to root out fraudulent providers.

Examples of this new, more proactive approach include the OIG's imposition of CMPs for physicians participating in kickback schemes and the recent exclusion of a nursing home provider for failing to adequately care for its elderly residents.

According to the IG, the latter exclusion illustrates that while financial schemes threaten the financial integrity of health care systems, abuse and mistreatment of seniors is just as egregious. To improve enforcement of quality of care, Rehnquist has instructed the OIG to scrutinize "patterns" of care in order to uncover systemic problems, especially in nursing facilities.

"I don't want to just cherry-pick at the symptoms," she asserts. "We need a holistic approach to determine patterns and systemic failures and address those failures with administrative authorities."

Rehnquist added that she plans to strengthen the OIG's partnership with state Medicaid Fraud Control Units and work with other federal agencies, law enforcement, and providers to develop an integrated response to quality-of-care issues.

Rehnquist also indicated that she recognizes the evolution of the government's compliance efforts, especially as those efforts relate to CIAs. The vast majority of providers "get it right" despite complex regulations, because they have good internal controls, she maintains. But while she plans to emphasize voluntary disclosure, she was equally emphatic that CIAs sometimes are required.

Rehnquist says the OIG plans to streamline the civil settlement process by dividing False Claims Act (FCA) civil cases into three broad categories. The OIG has determined that some FCA cases can be settled without a CIA; while in other cases, the resolution of the OIG's exclusion authorities can wait until after the settlement of the FCA case.

There is, however, a third group of cases where insufficient internal controls require that a CIA is imposed as "an integral part" of FCA settlements. Rehnquist says the OIG is developing criteria to be used to make those determinations.

In addition, Rehnquist announced that CIAs will be modified to reduce the financial impact of CIAs. Already, the OIG has amended compliance provisions contained in certain settlement agreements.

Now the OIG plans to change several of the independent review organization requirements in order to reduce costs and redesign the sample methodology to improve its effectiveness and reduce cost.

Specifically, Rehnquist says CIAs will require the use of a full statistically valid sample only in instances where the initial probe sample shows an unacceptable error rate. "If the error rate is within an acceptable mean, there will be no need for a full, statistically valid sample," she explains.

The OIG also will look for ways to increase reliance on providers' internal controls. Once finalized, these modifications will be incorporated into future CIAs and, where appropriate, will be made available to providers already operating under CIAs, she adds.

In addition to drafting compliance guidance for drug manufacturers, the OIG now is updating the existing guidance to make sure it reflects current regulations and payment systems, Rehnquist says. ■

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Inappropriate discharge

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charge is a predominant theme in the new workplan, particularly in the hospital environment. Not only are areas such as one-day stays targeted for scrutiny, but so are transfers within related parts of the system such as from an acute-care hospital to a rehab hospital or a skilled nursing facility within the same system, notes Homchick. "Hospitals should continue to monitor the transfer discharge process and length of stay and intensities to make sure they are operating appropriately without any trends," he says.

On the whole, however, it is somewhat more difficult to determine exactly what the OIG will actually stress, because the breadth and scope of the work plan is greater than in the past, warns **Paul DeMuro**, a partner in the West Coast office of Latham and Watkins. "I found it almost less helpful than in years past because you could tell less from it," he explains. "There is something here for everybody, and it would be hard to pick the top 10 or 15 areas."

DeMuro also notes that there is a higher percentage of items included in the workplan, such as restraint and seclusion at psychiatric hospitals, which are not Medicare reimbursement or fraud specific. That initiative comes up because of conditions of participation rather than direct reimbursement, he explains. The OIG's latest workplan highlights these specific areas:

- **One-day hospital stays.** The OIG plans to evaluate controls designed to ensure the reasonableness of Medicare payments for beneficiaries discharged after only one day in the hospital. It says it plans to concentrate on the adequacy of controls to detect and deny inappropriate payments for one-day stays.
- **Hospital discharges and subsequent readmissions.** The OIG plans a series of reviews that will examine Medicare claims for beneficiaries who were discharged and subsequently readmitted relatively soon to the same or another acute care prospective payment system hospital. Along with the Centers for Medicare and Medicaid Services, the OIG will determine if these claims were appropriately paid and examine the adequacy of existing system edits used to identify and review diagnosis and/or time-related admissions.
- **Consecutive inpatient stays.** The OIG will look at the extent to which Medicare beneficiaries receive acute care and postacute care through sequential stays in different settings such as skilled nursing facilities, long-term care hospitals, and prospective payment system-exempt units. The OIG notes that inpatient services may be denied based on peer review organization review for patients admitted unnecessarily for one stay or multiple stays.
- **Payments to acute-care prospective payment system (PPS) hospitals.** This update will examine diagnosis-related groups (DRGs) that have a history of abusive coding to determine whether some PPS hospitals continue to exhibit aberrant coding patterns. The study will incorporate the results of a recent review by the Payment Error Prevention Program on DRGs with significant patterns of coding errors.

The OIG also plans to examine the implementation of the critical access hospital program, which allows certain limited-service hospitals to be reimbursed for acute care on a cost basis rather than a prospective payment basis, and the effectiveness of CMS payment safeguard protections surrounding satellite units and "hospitals-within-hospitals." ■

Compliance survey

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effectiveness evaluations (65%).

Many compliance officers say this finding illustrates the almost dual role that compliance officers now face in getting their organizations ready for the sweeping privacy regulations, which go into effect in April 2003.

HIPAA clearly is a priority with all hospitals, says **Anthony Boswell**, chief compliance officer for Laidlaw in Arlington, TX. He says the initial challenge for hospitals was trying to determine what version of privacy and security regulations would be implemented and whether a privacy or security officer would be required. The challenge today is meeting obligations in the face of diminishing resources, Boswell says.

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According to the HCCA survey, the average departmental budget increased 12%, from roughly $293,000 last year to $327,000 this year. There is a wide disparity, however, with larger organizations averaging almost $690,000 and smaller organizations hovering around $130,000.

Further complicating budgetary matters for hospitals is the uncertainty surrounding the security requirements of HIPAA. A final regulation in that area is expected by the end of the year, but there is no guarantee that will happen. Privacy regulations are scheduled to become effective in 18 months and the transaction requirements are scheduled to take effect October 2002.

Further delays are still possible, however. For example, Sen. Larry Craig (R-ID) still is pushing a bill he introduced last spring that would establish a delayed compliance date for several areas including transactions and security. If that bill passes, the deadline for the transaction requirements would be extended until October 2003. House Ways and Means Committee Chairman Bill Thomas (R-CA) opposes the measure.

Last year, two-thirds of all survey respondents ranked program development/implementation as a top priority, but only 29% cited that as a top issue this year. The other priority issues cited this year — monitoring/auditing (83%) and education/training (76%) — were no surprise.

Many of the other trends uncovered by the survey were more subtle. The number of respondents who say their major constituencies have a basic understanding of compliance increased from 84% last year to 87% this year. The number of organizations that reported having an active compliance program in place increased from 55% in 1999 to 71% in 2000, and to 80% in 2001.

The percentage of organizations with a compliance officer job description inched up from 82% last year to 86% this year. **Sheryl Vacca**, a director with Deloitte & Touche in Sacramento, CA, says that any hospital that lacks a job description does not even have the basics in place.

According to Vacca, the first prerequisite to an effective compliance program is to be sure that everybody understands the responsibilities of the compliance officer. "If all you are doing is reporting and other activities, people do not understand what the job actually does," she asserts. ■

TAP agrees to settlement worth $875 million

TAP Pharmaceutical made history last week when it agreed to pay $875 million to resolve criminal charges and civil liabilities regarding drug pricing and marketing conduct connected to Lupron, a drug sold by TAP primarily for treatment of advanced prostate cancer in men. All sides now expect a flurry of similar settlements to follow elsewhere in the industry.

Under the settlement, TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act and pay a $290 million criminal fine. It also agreed to pay the government almost $560 million for filing false and fraudulent claims with the Medicare and Medicaid programs.

The company also agreed to a corporate integrity agreement (CIA) that changes how the company supervises its marketing and sales staff. The CIA ensures that TAP will report to Medicare and Medicaid the "true average sale price" for drugs reimbursed by those programs.

The investigation was triggered roughly four years ago when a urologist employed by Tufts HMO in Waltham, MA, told law enforcement authorities he had been offered an educational grant if he would reverse a decision he made on behalf of Tufts that it would cover only the less expensive competitor drug Zoladex.

While Medicare does not pay for most drugs needed by Medicare beneficiaries, it does cover drugs such as Lupron that must be injected under the supervision of a physician. Medicare paid for 80% of either the urologist's charge for Lupron or the average wholesale price (AWP) reported by TAP, whichever was lower, and the patient was responsible for the remaining 20% in the form of a copayment.

The government alleged that the AWP reported by TAP was significantly higher than the average sales price TAP offered physicians and other customers for the drug. The government also alleged that TAP marketed the spread between its discounted prices paid by physicians and the significantly higher Medicare reimbursement based on AWP as an inducement to physicians to obtain their Lupron business. ■