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New OIG Work Plan shows mix of old and new initiatives

HHS Inspector General warns that CMP authorities will be expanded

Days after the Health and Human Services' (HHS) Office of Inspector General (OIG) released a draft guidance for the pharmaceutical industry, drug makers fell under heavy scrutiny in the OIG's Work Plan for 2003. "Pharmaceutical companies have been on the radar screen for a couple years, and that is going to continue," says **Gary Eiland**, a partner with Vinson and Elkins in Houston. "But not to the exclusion of the more traditional areas dealing with hospitals and providers."

According to Eiland, many issues in the Work Plan fall in the latter category, such as diagnostic-related groups (DRG) window issues and hospital transfer issues, as well as patients discharged from the acute care setting and readmitted to a post-acute care setting. "One of the items even suggests that they were looking to see whether the three-day DRG window should be expanded to a 14-day window," he says. "That would be significant."

The OIG says this review will focus on DRGs that contribute to the highest percent of Medicare payments outside the DRG window. "From the standpoint of an investigation, that is a logical way to focus," says Eiland. "But at some point in time, I think you have to decide what falls in the DRG and what does not."

*See **Work Plan**, page 2*

OIG pharma guidance targets pricing, kickbacks

The draft guidance for pharmaceutical companies released Oct. 1 held few surprises. **Kathleen McDermott**, a partner with Blank Rome in Philadelphia, says her only real objection is the guidance's title, which she says may mislead health care providers into thinking it applies only to pharmaceutical companies.

"The health care community should not be misled that this is just about manufacturers and sales reps," says the former federal prosecutor from Maryland. "Many of the issues highlighted in the guidance apply across the board to physicians, hospitals, and other health care providers and

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Strategies for internal compliance investigations

While internal investigations are not listed among the seven elements of effective compliance in the Federal Sentencing Guidelines, **Steven Ortquist**, chief compliance officer at Banner Health System in Phoenix, says the need for investigations of suspected wrongdoing is clearly implied in the sentencing guideline's description of what a compliance program requires.

"Both mechanisms for ensuring compliance and corrective action, two of the seven compliance program elements, assume the existence of an ability to investigate possible noncompliance," he explains.

One of the most important goals of an internal investigation is to determine whether a suspected violation of law or compliance program requirement has in fact occurred, Ortquist says. "However, this threshold determination is only part of what an internal investigation must be designed

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Work Plan

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In the area of Medicaid, the OIG also plans to look at the three-day stay requirement, Eiland notes. Some state Medicaid programs have a similar DRG window. Basically, the OIG wants to see if some of the same problems exist for Medicaid payment in those states that the OIG previously uncovered regarding Medicare, according to Eiland.

He says the OIG appears to be adapting many of the items it previously examined under Medicare, such as graduate medical education, the DRG window, patient transfers, and credit balances. "Basically, it is some of the old issues applied to a new setting," he says.

Gabe Imperato, a partner with Broad and Cassel in Ft. Lauderdale, says the Work Plan shows that the OIG is becoming more sophisticated in its focus. Specifically, he points to the OIG's scrutiny of physician ownership of ambulatory surgical centers, the cost of surgeries, and medical necessity of inpatient psychiatric stays. Diagnostic testing in emergency rooms also is somewhat new, he adds.

Health care attorney **Howard Young** of Arent Fox in Washington, DC, says the Work Plan also includes an increased focus on quality-of-care and quality oversight reviews, as well as hospital privileging issues.

"Focusing on quality oversight issues is not new," Young observes. He points out that the government clearly has been focusing on quality of care issues related to nursing homes and continues to do so. "On the hospital side, it is somewhat new," he cautions.

The former OIG attorney notes that, with respect to enforcement, there has not yet been any successful effort using the False Claims Act on quality-of-care issues related to hospitals. He says the new Work Plan may help get "creative juices flowing" in that regard. Whether there is any merit to that approach is another matter, he adds.

Imperato says it will be important to watch how much enforcement takes place through the civil monetary penalty (CMP) laws and exclusion statutes. HHS Inspector General Janet Rehnquist reiterated her intent to expand the use of those authorities earlier this month.

Young notes that for more than a year, the OIG has publicly touted that approach. He says some CMP authorities related to kickbacks have been on the books since the Balanced Budget Act of 1997 that have not been used very much. "Clearly, the [OIG] Office of Counsel is gearing up to use that authority with more regularity," he warns, "and success breeds success."

According to Young, that CMP basically amounts to an intermediate sanction. "It is short of a criminal prosecution," he explains. "But it is not a free pass, either." He also notes that the OIG has increased staff in the Office of Counsel to pursue those cases.

To the extent that health care fraud enforcement continues to be a priority, Imperato predicts the OIG will spearhead that initiative more than it has in the past, simply because there are more competing priorities for the Department of Justice.

According to Young, False Claims Act cases that are not pursued by the Department of Justice, and possibly fraud cases involving individuals pursuant to settlements with an institution, also may be a focus of OIG attention.

Imperato says that, while he has seen some increased activity over the past year in connection with physician kickback cases, the jury still is out on how broadly the OIG will use its CMP authority. "I am waiting to see a little more pervasive impact than I have seen so far," he says. "Maybe it is on the horizon." ■

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Internal investigations

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to identify," he adds.

Ortquist says an internal investigation also should determine the scope of the violation, the scope of any harm that was caused, and identify the person or persons involved in activities that created the violation.

According to Ortquist, an effective investigation may allow an organization to identify and correct violations before they ever come to the attention of government investigators, letting providers take full advantage of self-disclosure protocols when this is an appropriate response.

Likewise, he says an effective internal investigation also may allow an organization to head-off a *qui tam* lawsuit that might otherwise be filed. "Even when an internal investigation protocol must operate in parallel with a government investigation, having such a protocol in place may allow an organization to work with the government in defining the scope and direction of the investigation," he says.

When developing a compliance program, Ortquist says organizations should consider developing a plan for conducting internal investigations. "The internal investigation plan could take the form of a formally adopted policy and procedure or it could simply be a guiding document for the compliance program," he explains.

Ortquist says such a plan will help to assure that internal investigations are methodical, consistent and thorough. He notes that conducting internal investigations according to a plan also can protect the compliance officer from allegations that he or she neglected his or her duties if the investigation later comes under scrutiny.

"Conducting an appropriate and thorough internal investigation is often as much an art as it is a science," Ortquist contends. Because the scope and direction of each investigation will turn on a specific set of facts and circumstances, he says the plan should offer the compliance officer discretion at each step to determine whether an element of an internal investigation is necessary and to determine how each element of the investigation will be conducted.

According to Ortquist, the steps and strategies outlined below all can be included in an organization's internal investigation plan:

- **When a report is received, take steps to preserve evidence.** When the compliance department receives a report of possible impropriety, the compliance officer should immediately consider whether any steps are necessary to preserve possible evidence, says Ortquist. "Corporate scandals in recent months have been a reminder of the consequences of destroying evidence after a government investigation has begun," he warns.

He says possible steps might include restricting access to evidentiary material, such as revoking computer passwords, sequestering medical or billing records, or even removing an employee who is suspected of wrongdoing while the investigation is under way.

While fixing problems is part of compliance, in the early stages of an investigation, compliance officers often will need to decelerate the desire of those involved to get things fixed as soon as possible, Ortquist says. "Delaying a 'fix' does not mean that known improprieties should be allowed to continue," he explains. "Instead, it may be necessary to halt the activities in question while an investigation is undertaken."

- **After achieving a basic understanding of the possible problem, develop a basic understanding of the applicable rules.** Health care compliance investigations often involve possible noncompliance with complex laws, regulations, or billing rules. Ortquist says that makes it important for compliance investigators to have immediate access to resources that will allow the investigator to research the laws, rules, and regulations in question.

While thorough research is necessary to a comprehensive compliance investigation, Ortquist says the need to conduct this research must be balanced with the need to work quickly. He says one way to achieve this balance is to use staff or outsiders who have a full understanding of the rules in question to assist compliance investigators. In some circumstances, these individuals might even be able to assist in conducting portions of the investigation, he adds.

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♦ **Work quickly, but be thorough.** Ortquist says it is important to work quickly, especially during the initial stages of the investigation because evidence is easier to find if it is collected soon after the alleged impropriety occurs. "With time, evidence will go stale or disappear, and the memories of those who might have witnessed the wrongdoing will dim or be corrupted by conversations with others about their recollections of what occurred," he warns.

In addition, many of the regulatory schemes that affect health care organizations require organizations to report discovered violations soon after they are discovered. For example, Drug Enforcement Administration (DEA) regulations require prompt reporting of theft or diversion of controlled substances to the diversion unit of the DEA.

Organizations that discover legal violations that result in false claims liability may benefit from reduced penalties for self-disclosure if the disclosure is made within 30 days of the discovery of the violations, he adds.

While it is important to work quickly, Ortquist says it also is important to establish realistic expectation about the investigative process. Completing a thorough investigation of an alleged compliance violation sometimes can take months or even years, he says. He points to one experienced practitioner who has noted that a typical internal investigation will take between three months and two years to complete.

"Work quickly, but don't rush the process," he concludes. "While it is important to draw conclusions, it is equally or even more important to make certain that those conclusions are correct." ■

Pharma guidance

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their arrangements and relationships with pharmaceutical manufacturers."

"The discussion on kickbacks and drug samples applies to many aspects of the health care industry," she adds. McDermott says that is where the rubber is going to hit the road for hospitals because of their formularies, and for physicians because of their prescribing practices. "I think it is a particularly good discussion on those issues," she says. "I think it is a welcome discussion."

Health and Human Services (HHS) Inspector General **Janet Rehnquist** says the sheer size of the pharmaceutical industry makes it a high-profile target. "The real money is in the pharmaceutical industry," Rehnquist said when she released the guidance at the joint American Health Lawyers Association/Health Care Compliance Association conference in Washington, DC, on Oct. 1. "Obviously, the need for compliance measures, oversight, and enforcement is paramount."

While Medicare pays for only a limited number of drugs, about $700 million in Medicare spending in 1992 leaped to $5 billion in 2000. "That number is staggering considering that Medicare only covers a handful of drugs," says Rehnquist. ■

IG highlights central areas in pharma guidance

At the joint American Health Lawyers Association/Health Care Compliance Association conference in Washington, DC, Health and Human Services (HHS) Inspector General **Janet Rehnquist** highlighted three central areas in the recently released draft guidance for pharmaceutical companies:

♦ **Average Wholesale Price.** The first area cited by Rehnquist is the pricing issue where there is considerable focus on average wholesale price, the methodology used to pay for drugs. "Companies are responsible for the integrity of the data that they provide to the clearinghouse, which establish the base for reimbursement," she explains.

♦ **Kickbacks.** The OIG's second main area of concern is kickbacks, Rehnquist says. "Employees and agents must be aware of the anti-kickback statute and the constraints that that statute places on marketing and promotion of their product," she warns.

"Manufacturers need to pay particular attention to payments for consulting, meals, and entertainment in conjunction with marketing, gifts, and business courtesies and the sponsorship of education and grants," she adds.

♦ **Samples.** "Last but not least, we provide guidance on the use of free samples," says Rehnquist. "Free means free," she asserts. "If a sample is given free to a physician, it should be free to the patient, and it should be free to the government." ■