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Pharmaceuticals continue to top list of fraud initiatives

Physicians and hospitals are not immune from scrutiny, warns federal prosecutor

Government health care fraud investigators continue to maintain a high level of interest in issues related to pharmaceuticals, experts say. Indeed, according to *qui tam* attorney **Marc Raspanti** of Miller Alfano in Philadelphia, many complex schemes involving physicians and pharmaceutical companies that still are under seal will begin to surface later this year.

Margaret Hutchinson, assistant U.S. attorney in Philadelphia, says one overriding concern of the government's is that physician judgment may be compromised by the approach pharmaceutical companies use to push a particular drug. Many of those concerns will be spelled out in significant detail when the Department of Health and Human Services' Office of Inspector General (OIG) releases its draft guidance for the pharmaceutical industry later this year.

In the meantime, Hutchinson says many of the issues that hospitals should be wary of are spelled out in the TAP Pharmaceuticals corporate integrity agreement (CIA) with the OIG, announced in October 2001 and posted on the agency's web site.

Here are some of the specific questions that Hutchinson says compliance officers should pose regarding the purchase of drugs:

- Who is in charge of that decision?

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OIG nixes potential copayment waiver

In its latest advisory opinion dealing with the potential waiver of copays, the Health and Human Services Office of Inspector General (OIG) determined that an X-ray provider's proposal to waive the Medicare Part B copayments applicable to the portable X-ray services it provided to nursing home patients potentially could violate the anti-kickback statute.

The X-ray provider proposed to waive the copayments of nursing home patients who are provided full, dual coverage by Medicare and Medicaid. While Medicaid frequently pays the Medicare copayment owed by dually covered beneficiaries, it

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HHS offers four steps to aid HIPAA compliance

If hospitals have not already requested an extension for the transaction and code sets required by the Health Insurance Portability and Accountability Act (HIPAA), now is the time to do so, says **Donna Eden**, senior attorney with the Department of Heath and Human Services (HHS). "There is no downside to submitting an extension," she says. "There are no costs involved."

Eden says providers should pay close attention to the extension form and sit down with the people in their organization who are responsible for actually making the HIPAA transition happen, because the form provides concrete signposts, goals, and check-off points. "If you have had trouble getting the attention of your upper management, this form should help," she adds.

Here are four more steps Eden says will assist providers preparing for HIPAA compliance:

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Pharmaceuticals

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- What went into that decision making?
- What went into the contract negotiations to put the drug on the formulary?
- Did that induce the person to possibly compromise what otherwise would have been a different medical choice in terms of the prescribed drug?

According to Hutchinson, these questions were central to the investigation that led to TAP's $875-million settlement with the government last year. "They are very interesting issues that are not put to rest with just the TAP case," she warns.

Former state prosecutor **Carolyn McElroy** argues that the TAP model plays out differently in the hospital setting because drugs are not reimbursed separately. "Hospital reimbursement for drugs is based on DRGs with a handful of exceptions," says McElroy, who helped shape the pharmaceutical-fraud initiative before leaving for private practice. "That gives hospitals an incentive to buy the cheapest overall effective product."

McElroy, now with Mintz Levin in Washington, DC, also contends that it will be difficult for the government to argue that hospitals cannot legally consider the cost of a product or prosecute a cost-based decision as if it were an "inducement." After all, state and federal government purchasers consider cost when buying pharmaceuticals, she points out.

McElroy says proving intent by a hospital gets even more complicated because hospitals typically use buying groups for pharmaceutical purchases, and those buying groups actually make the decisions on what drugs are available for the hospital to buy. She argues that it will be difficult for the government to hold the hospital responsible for decisions on which a drug is purchased when it had no real knowledge about why a certain brand or drug was chosen, and its choices may have been limited by the buying group's offerings.

Research in the hospital setting is another compelling issue right now, especially where teaching hospitals are concerned, says Hutchinson. Numerous issues related to research can spell trouble for hospitals, she says. Three of those issues include quality of care, merging of patient populations, and whether the researcher who receives a government grant is actually the one doing the research, she says. ■

How to assess on-line compliance training

Emerging on-line training programs now offer hospitals and other providers considerable training opportunities. But facilities must assess these programs carefully before making a purchase, warns **Dan Roach**, vice president and corporate compliance officer at the San Francisco-based Catholic Healthcare West (CHW), which operates nearly 50 acute-care facilities throughout California and the West Coast. "On-line training can be very expensive," he says, "but it does not have to be."

Roach says the first question to address when developing an on-line capability or on-line training resource is the substantive content and the target audience. Other key considerations include the accuracy of the content, how the material was developed, how it is maintained, and how it is updated.

"Look at the content and complexity of the program," says Roach. He points out that some groups of employees will require very basic education, while others will need fairly sophisticated education. "Make sure that you are getting the right mix," he says.

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Roach says hospitals can determine whether it is an effective teaching tool by having some of their employees use it before it is purchased to find out if it is something that really helps them learn and retain the information.

"In my experience, we don't spend enough time evaluating some of these tools," says Roach. "We have a tendency to focus on the graphics or the price," he adds. "You may pay twice as much money for a product, but if it is a lot more effective in delivering the message, it may be the better deal in the long run."

How quickly the program can be accessed is another important consideration, Roach says. That is particularly true if the educational focus is patient care personnel who may only access the program intermittently. "You want something that they can get into fairly rapidly," he says, "and maybe something that can be bookmarked."

According to Roach, all of these considerations should go into the overall cost of implementing an on-line training program. "It is not just the cost of the software and what you are paying the vendor," he says. "All of these things go into assessing the value of what your product is ultimately going to cost your organization."

Here are some other key considerations:

- **Ensure adequate contracting.** Roach says it is very important to have a clear contract that specifically delineates performance expectations and what will be delivered in terms of a product. Also, Roach says he looks for a mechanism to guarantee that the software he purchases will be available a few years down the road if the business encounters difficulties.
- **Establish explicit performance standards.** Roach says it is important to talk to your information systems people and make sure they understand how quickly you can access the information, how long it takes to log in, and similar considerations. "That is an indication of the impact it will have on your productivity and the utility of the product," he explains.
- **Know system limitations.** According to Roach, even a large, sophisticated system such as his can encounter difficulties when it comes to having employees access these programs. "We have a long way to go in getting all of our employees access," says Roach. He says hospitals should be cautious about promises from information systems staff in this regard.
- **Assess functionality.** Another important question is whether a hospital will have the technical staff to support the program internally and whether there is an adequate relationship with the outside vendor to make sure it can provide adequate support.
- **Assess human resource issues.** "If you are going to provide education, you need to have a mechanism for tracking and reporting that education," says Roach. Many hospitals already have systems for doing that, but he says it must be determined if the systems can be integrated. "Education is great," he says. "But the OIG is always going to want to see what you have done, and you need to be able to do that."
- **Address personnel management.** A final area that must be addressed is personnel management, says Roach. If hospitals have a program that can be accessed 24 hours a day, seven days a week, they may want to let employees access it from home. However, that requires that you can manage its use and that you understand the budgetary impact. "All of these issues bring consequences and costs for the organization if they are not carefully managed," he says. ■

OIG seeks input to update hospital guidance

The Department of Health and Human Services' Office of Inspector General (OIG) is seeking recommendations from hospitals in order to update the compliance guidance it first published February 1998. The solicitation for recommendations to revise that guidance follows "recent changes in regulatory requirements and the industry generally," according to the OIG.

"The reimbursement world has changed a lot since they came out with their original guidelines," says **Dennis Barry**, a partner with Vinson and Elkins in Washington, DC. He points out that cost reimbursement is almost totally irrelevant now, while many other issues have become far more important.

The hospital outpatient prospective payment system (OPPS) is one major change, but there are

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others too, he adds. For example, the issue of one-day stays is not addressed in the existing guidance but continues to show itself as a major issue confronting hospitals. Specifically, the OIG says it intends to evaluate the impact of the OPPS, which includes a long list of new potential risk areas.

The OIG also noted advanced beneficiary notices, charge description master, coinsurance collections, transitional corridor payments, multiple-procedure discounting, packaging of ancillary services, observation status, readmissions, inpatient-only procedures, medical record documentation, and hospital and physician coding.

The OIG's solicitation of information was published June 18 in the *Federal Register* and is available at the OIG's web site at www.hhs.gov. ■

Advisory opinion

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does not pay the Medicare copayment for portable X-ray services provided by non-Medicaid-approved providers. Absent the waiver, the recipient would be liable for the copayment.

In making its decision, the agency expressed concern that the proposed waiver would not be based on a good-faith, individualized determination of need and would not be applied uniformly, since the provider intended to waive copayments only for nursing home residents.

The OIG also noted that the nursing home, which served as a potential referral source for the X-ray provider, would benefit from the waiver through decreased administrative costs and increased fees.

The advisory is a fairly straightforward application of the law, according to **Ankur Goel** of McDermott Will in Washington, DC, who says the provider basically was trying to get business it could not otherwise get because of a complicated Medicaid rule in a particular state. While the rules in question may not make sense to the provider, there was not a strong basis for OIG to waive the prohibitions, he says.

Technically, copays can be waived only on an individual financial basis, Goel notes. "Even if you think the state law is unfair and that the patient should be covered under Medicaid, that is not a sufficient reason to remove the restriction."

Goel adds that, in most cases, the OIG's concern about waiving copays is overutilization of services. In this case, he says, the larger concern appeared to have less to do with overutilization than with competitive issues. "You don't really see in the opinion any direct explanation of what the harm is to the program," he says. "It is written more in terms of harm to competitors." ■

HIPAA compliance

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- **Work with your IT staff and vendors.** Eden says HHS is hearing complaints about vendors that claimed to be HIPAA-compliant two years ago but are not. "Two years ago, everybody was running around with little rubber hippos and saying their products were 'HIPAA-compliant' before the final rules were published," she notes. Many of those vendors, it now turns out, are not able to offer HIPAA-compliant software. "Put pressure on them to get the job done right," she advises.
- **Contact your trading partners.** Eden says hospitals also should contact all of the entities they exchange health information with to coordinate their various schedules. "Start working out the details so that you will be ready to test by April 2003," she says.
- **Support your standards development organizations (SDOs).** According to Eden, SDOs also welcome participation. SDOs are volunteer groups chartered by the American National Standards Institute that are responsible for maintaining the actual standards that were adopted as the HIPAA national standards, she explains. "They love volunteers," she says, adding that working groups offer hospitals multiple opportunities to participate.
- **Use this delay time to reach compliance.** Finally, Eden says, providers should keep in mind that it really *is* happening. She reports that she is now hearing from many institutions that have implemented a significant portion of the HIPAA transaction requirements.

"They find not only does it actually save money, but it also improves the quality of care," she says. "There are unexpected benefits from making this transition." ■