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OIG to release sweeping draft guidance for pharmaceuticals

Hospitals and physicians also will be immediately affected, health care attorneys say

Department of Health and Human Services Inspector General Janet Rehnquist is set to release the Office of Inspector General's (OIG) long-awaited draft guidance for the pharmaceutical industry tomorrow. "It is fair to say that depending on what the OIG says, the basic rules of the game could be fairly significantly impacted," says **Bill Sarraille**, a health care attorney with Arent Fox in Washington, DC.

According to Sarraille, a major focus of the draft guidance will be not only the practices of pharmaceutical companies but also practices as they relate to relationships with their customers such as hospitals and physician practices.

From a hospital perspective, the guidance likely will shed some new light on how pharmaceutical companies can price products to hospitals and how discounts can be packaged, Sarraille says.

For physician practices, the guidance will have an effect on the physician staff of hospitals, how they interact with pharmaceutical companies, and possibly the motivation of physicians to pressure hospitals to make particular purchases, Sarraille says.

"It could mean even the nature of the exchanges and the basic sales calls by reps to hospitals will change," he adds, "so that you can get this kind of lunch but not that kind of lunch and

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Pros, cons for compliance officers' expanding role

Kristin Jenkins, compliance and quality officer at JPS Health Network in Fort Worth, TX, says that if she has learned any single lesson from the business ethics debacles of the past year, it is the value of remaining focused as a compliance professional.

At the same time, she says, the expanding role of compliance officers makes that an increasingly delicate balancing act.

"I believe the expanding role of compliance officers will bring with it many new conflicts of interest," she argues. Nevertheless, Jenkins encourages other compliance officers to accept

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HIPAA: Preemption issue looms for providers

One of the thorniest issues providers face in implementing the Health Insurance Portability and Accountability Act's (HIPAA) privacy laws is the issue of preemption. In short, HIPAA's privacy standards will preempt any contrary state laws unless those state laws are more stringent.

If that sounds simple, it's not. One law firm that analyzed preemption for the nation's largest insurers had to field a full-time staff of 14 attorneys for several months to study the issue fully.

Two individual states' experiences illustrate the complexity. **Clark Stanton**, a partner with Davis Wright Tremaine in San Francisco, worked with the California Health Care Association to develop a California Privacy Manual that included preemption analysis. One of the first things Stanton hoped to find was a partner from the state.

"We thought that working with the state might be valuable in producing the analysis," he says. "The problem we ran into right at the start is that

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Draft guidance

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this kind of freebie but not that kind of freebie."

Joe Metro, a partner with Reed Smith in Washington, DC, says one major focus of the guidance will be kickback issues, which are being scrutinized closely by government investigators. "I would think from a hospital's perspective, the things that are going to be of the most interest will be kickback relationships, educational grants, pricing relationships, and discount disclosure," he says.

Another important area will be clinical investigator relationships. "I suspect we will see some of that too, and that will be of interest to hospitals," he says.

Metro says he expects the guidance to be somewhat general in nature. "I don't think they are going to bless any particular substantive standards in terms of educational grants," he explains.

The OIG's guidance comes a few months after the Pharmaceutical Research and Manufacturers Association (PhRMA) in Washington, DC, released revised marketing guidelines for its members. Like the OIG's guidance, the PhRMA code is voluntary. However, it was widely embraced by the pharmaceutical industry.

"PhRMA obviously tried to preempt what it was concerned could be some very strict guidance that would cut back on sales practices and pricing approaches which its members think are critical to function competitively in the marketplace in the code they put out," says Sarraille.

Wendy Goldstein, a heath care attorney with Eptein, Becker and Green in New York City, says the major distinction between the OIG guidance and the PhRMA code, which is much narrower, is that PhRMA's code essentially is limited to the interaction between the pharmaceutical industry and the physician.

"The issue really becomes the scope of the PhRMA code and the scope of the OIG compliance program," Goldstein explains. "You are going to see a much broader guidance from the OIG because it is built around the Federal Sentencing guidelines."

Goldstein says the OIG's guidance will cover appointing a corporate compliance officer, establishing committees, and implementing training, as other compliance guidances have done. However, she predicts that it likely will differ in that it will include more specific examples for an indirect biller situation since, unlike hospitals, pharmaceutical manufacturers do not submit anything directly to the government.

She says it also is likely to be much more specific than the other OIG guidances.

The OIG's pharmaceutical guidance has been in the works for more than a year. The agency published a notice in the *Federal Register* seeking information and recommendations for developing voluntary guidance for the pharmaceutical industry in June 2001. It is expected to be posted on the OIG web site at www.oig.hhs.gov tomorrow and published soon in the *Federal Register* for formal comment. ■

Hospitals establish pharma guidelines

With pharmaceuticals becoming a high-risk area, some hospitals increasingly are focusing attention in this area. Many of them have tried to establish policies that express what they consider appropriate practices.

A case in point is Lovelace Health Systems in Albuquerque, NM. "We did a major roll-out of our gifts and favors policy," says **Alison Maney**, compliance officer at Lovelace. "We are probably one

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of the strictest in the nation."

Maney says the policy has met some resistance among the physician staff. However, physicians now are regularly calling to ask for guidance about what is permissible.

"We took a hard line in this area," says Maney. "We even cut out food in the clinics." She says physicians also were implored to be cautious on their own time. Physicians were warned that investigators sometimes will subpoena pharmaceutical company records and get the names of every provider who has been receiving gifts under the table.

Maney says she warned physicians that her role is to inform them of what is and is not legitimate, while their responsibility is to stay within those boundaries. ■

Preemption

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there was no one at the state to work with." Now, there is an Office of HIPAA implementation, he adds, but the primary mission of that office is to advise California state agencies. "We really don't have a dance partner with the state," he says.

According to Stanton, California has an existing state privacy scheme that includes a fairly comprehensive confidentiality of medical information act, as well as a separate statutory scheme that deals with mental health information. "You have two primary schemes to take into consideration," he says.

As an example of how HIPAA and California state laws interact, Stanton points to subpoenas and other discovery requests. "In this instance, we found that California law was more stringent than HIPAA," he says.

The HIPAA requirement is that a requesting party must make a reasonable effort to notify the person whose protected health information is the subject of the subpoena or discovery request. Meanwhile, the California law had an existing requirement that authorities must actually serve the individual whose records are being requested, advising them that a subpoena has been issued and notifying them about the process for challenging that discovery attempt.

"That is a fairly clear-cut example of a state provision being more stringent and providing greater protection," says Stanton. However, there are various provisions in HIPAA permitting disclosures to law enforcement, not all of which are set forth in California law, he adds.

In that situation, Stanton says you have to ask whether the California law actually is intended not to allow for those disclosures. "As with HIPAA, it is set up in a way that if it is not permitted, you have to assume that it is prohibited," he says.

This became an issue in terms of marketing and fundraising because California law does not have an equivalent provision for the release of information for marketing and fundraising in the same way that HIPAA does.

According to Stanton, the provision of California law allowing the HIPAA provisions to take effect notwithstanding the silence of California law turned out to be controversial but, in his view, a correct interpretation of HIPAA.

Jean Quarier, associate counsel at the New York Department of Health, notes that there is saying that if you can make HIPAA preemption rules apply rationally in New York state, you can make them apply rationally anywhere.

To illustrate her point, Quarier points to two New York state laws. One law guarantees New Yorkers the right to access their records when they seek care for medical, dental, social work, pharmacies, chiropractors, and other health care providers. With some exceptions, personal notes and observations of the provider are not included under this right of access.

New York state law does permit denials of information in certain circumstances, she adds. One of those exceptions is when the information could cause substantial and identifiable harm to the patient or others, which outweighs the patient's right of access.

The second exception is if access to this information would have a detrimental effect on the care of a minor. The review policy is that the state appoints a committee of several providers to review the denial, and if the committee upholds the denial, the patient must seek a court order.

In relation to HIPAA, Quarier says it became

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clear that, in some ways, HIPAA provides more access. For one thing, it covers a larger data set. Unlike the New York state law, HIPAA also includes notes and observations except for psychotherapy notes.

"It would seem, at first blush, that HIPAA would provide more access," Quarier says. "However, there may be some cases where some psychotherapy notes contain objective information, which could not be classified as a provider's personal notes and observations."

In those specific circumstances, HIPAA actually might not provide broader access, says Quarier. "You can see how this is getting to be a very fact-specific analysis," she asserts. ■

Expanding role

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expanded responsibility. For one thing, expanding her responsibilities has given her a better perspective on day-to-day problems that arise for middle management and senior management.

According to Jenkins, ethical complications can arise when the role of a compliance officer expands past a "pure compliance program." Some of those complications are obvious, she told participants in a Health Care Compliance Association audio conference Sept. 24.

For example, when she took over the area of medical records, that included coding. "I could not very well audit my own coders and look objective," she says. "These are issues that I don't see as solvable internally."

However, other conflicts that arise every day are manageable if compliance officers focus on disclosure, says Jenkins.

For example, compliance officers who are responsible for a quality program in an organization also may be responsible for accreditation from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

"If you have JCAHO come into your organization and look for your compliance with their standards, you are obligated to be as upfront and complete in your responses and as accurate as possible in a business-ethics sense," she says.

As a compliance officer, that would be no problem, she says, because compliance officers would be monitoring pieces of those standards or conducting audits that may relate to JCAHO standards as well as others.

However, when a team is there to accredit an organization and performance evaluations are tied to JCAHO, there may be a conflict because compliance officers may have an incentive to be less than forthcoming in order to benefit themselves.

"Discussion and disclosure is key in managing your business ethics," argues Jenkins. By that, she means actually discussing the pros and cons of a specific course of action, she says. "This is so difficult for leaders sometimes to do, to talk about the potential downfalls and potential risks of a course of action."

Jenkins says that some board members tend to get caught up too much in the risks. But she adds that most sophisticated leaders in an organization will understand that operating a business carries inherent risks. "They each have their own level of willingness to engage in that risk," she says.

According to Jenkins, compliance officers can avoid many business-ethics issues simply by being upfront about potential risks.

"You have a room full of people who can engage what they believe will be the right thing to do," she says. "That many heads are usually better than one."

Jenkins says those discussions can be extremely beneficial to everyone in the organization and also can provide the board with a new level of information so that if something does happen in the future, they understand and have made an informed decision to accept that risk.

"I believe that compliance officers are the COOs and CEOs of the future," Jenkins maintains. She says they are uniquely positioned to develop relationships with boards and understand issues across an organization.

"I believe the government had an intent to create a new generation of leaders in health care when they began recommending or prescribing the engagement of a compliance officer in health care organizations," she argues.

Jenkins says that she believes the government wanted individuals at a high level who would understand the issues facing entities and who had a focus at the outset of their executive careers on business ethics as well as business practicalities. ■