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Confidentiality regs may cost industry $40 billion

Final HHS regulations may spawn a whole new industry unto itself, experts warn

The Department of Health and Human Services' (HHS) latest estimate that patient confidentiality regulations will cost the health care industry a tidy $3.8 billion may be off by a factor of 10, according to the Blue Cross and Blue Shield Association (BCBSA) and other groups. They say the real cost may top $40 billion over five years.

According to the Washington, DC-based BCBSA, retraining and recertifying employees, hiring privacy officials, upgrading systems, and making other changes in infrastructure alone would cost $23 billion. The requirement to track all disclosures of information would add $9 billion while the provision to make providers liable for compliance of their business partners would tack on another $4 billion.

House Ways and Means Health Subcommittee Chairman Bill Thomas (R-CA) grilled HHS officials on the potential cost of the regualtions at a hearing before his subcommittee Feb. 16. He also warned HHS Assistant Secretary for Planning and Evaluation Margaret Hamburg not to let the confidentiality regulations go the route of the compensation portion of the physician self-referral regulations — otherwise known as Stark II — which have been in the drafting stage for nearly a decade. "We have been chasing that elusive butterfly for seven years now."

Healthcare Leadership Council president **Mary**

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UC settlement raises doubts about voluntary disclosure

A recent big-money settlement is raising disturbing questions about the value of voluntarily disclosing potentially damaging information to the federal government, and exposing your facility to whistle-blowers.

In that settlement, the University of Chicago, its affiliated hospitals, and a faculty physicians' group agreed to pay the government and the state of Illinois a total of $10.9 million to settle charges that they improperly billed Medicare and Medicaid an unspecified amount for outpatient and inpatient

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OIG puts spotlight on office rental arrangements

Physicians who rent office space to health care suppliers and providers should make sure the rental amounts reflect fair-market value for the space actually used by the supplier, according to a special fraud alert issued by the Department of Health and Human Services' Office of Inspector General (OIG) Feb. 22.

Stuart Kurlander, a partner with the Washington, DC-based law firm Latham and Watkins, says the alert is "a double-edged sword."

On the one hand, Kurlander says, the fraud alert includes a useful clarification that providers can use as an audit tool to ensure that their contracts with suppliers are in compliance with federal laws.

On the other hand, he says the Health Care Financing Administration could just as easily accomplished this through a program memorandum.

Kurlander says the alert also clarifies the ability

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Grealy, who testified at the hearing, says health care providers should brace themselves for precisely that scenario. By the time HHS gets the final rule out, Grealy says the health care system will have changed profoundly.

"You're taking a snapshot of what the health care system looks like today, but you can't possibly account for what technology is going to allow for tomorrow," she warns. "The more prescriptive you try to make the regulations, the more you restrict what may be valuable uses of patient data."

Worse yet, Grealy says the confidentiality regulations may spawn a whole new industry. "It reminds me of when the DRG system took effect and medical records suddenly had to be converted into proper codes. Then we moved to the fraud abuse compliance officer." She predicts these regulations represent a third wave.

Thomas and his colleagues may have little to say on the matter, however. Last year, Congress missed its deadline to pass confidentiality legislation mandated by the Health Insurance Portability and Accountability Act of 1996. That passed responsibility to HHS to write regulations that would cover medical records and health information maintained or transmitted electronically. The extended comment period for HHS' proposed regulations ended last week.

From a provider standpoint, passing the torch to HHS has several major flaws.

The biggest one is that the HHS regulations will not pre-empt state laws. Only a law passed by Congress could have done that. Instead, HHS' federal regulation will only pre-empt state law when the federal provision is more stringent.

Grealy and others say the result may be a nightmare for health care providers. Not only will providers have to master both state and federal confidentiality laws, they will have to master a patchwork of state and federal regulations to determine which law supercedes the other.

"You will still have health care providers and insurers and everyone else involved with having to comply with the existing 50 state laws and trying to figure out which are more strict or less strict, and also the federal laws, as well," warns Grealy.

Health care providers' fears are probably well-founded. Hamburg is already on record as saying that a health care provider that knowingly obtains or uses health care information in violation of the standards will be subject to criminal felony penalties. Penalties should be higher when violations are for monetary gain, she added.

Alissa Fox, executive director of BCBSA, says the proposed rule has three major problems in addition to the pre-emption of state law. First, the partnership provisions of the regulation would require providers to enter into prescribed contracts with all of their business partners and would be subject to penalties if they "knew or reasonably should have known" about privacy violations committed by their business partners.

"The definition of business partner is so broad that physicians could be the business partners of independent laboratories, health plans could be the business partners of their lawyers and accountants, and hospitals could be the business partners of independent physicians that practice within their walls," Fox asserts.

Second, Fox says the proposed regulation instructs providers to use or disclose only the minimum information necessary to accomplish a given purpose and discourages the exchange of the entire medical record. "At first blush, this standard seems to be a perfectly reasonable, common-sense provision." Operationally, though, it would be a nightmare, she adds. It would be impossible to implement a legal standard that only

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the minimum information is used or disclosed. That's because the standard applies to the use of information as well as disclosure, and that definition of disclosure includes broad terms, such as "provision of access to."

"This standard would require a massive reorganization of workflow as well as a possible redesign of physical office space, and would jeopardize the timeliness of patient care, benefit determinations, and other critical elements of the health care system," Fox warns.

Finally, Fox argues that the proposed rule includes a definition of "health care operations" that is exempt from the regulation and is far too narrow. "The current definition of health care operations misses important functions," she argues. "As a result, covered entities may have to solicit authorizations for certain functions or track disclosures as part of routine operations."

There is no shortage of other potential violations that could trip up hospitals and other providers. Here is a short list of requirements providers would be forced to meet:

- Obtain new authorization from consumers before using or disclosing information, except for purposes of treatment, payment, health care operations, and other limited circumstances.
- Allow individuals to inspect, copy, and amend much of their medical information.
- Track all disclosures made other than for treatment, payment, and health care operations.
- Recontract with all business partners to require them to use and disclose information according to the new privacy rules and assure that business partners are complying.
- Institute procedures to assure that only the minimum information necessary is used or disclosed for a given purpose.
- Designate a privacy official and train staff.
- Follow specific rules before using protected health information for research.
- Develop a host of new policies, procedures, and notices.

"Just on the face of it, you can see this isn't going to work," concludes Grealy. "This will be a whole new industry by the time this regulation is final." ■

Rental arrangements

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of suppliers to pay certain individuals in the physician's office to administer those programs, as long as the payment is consistent with the actual time spent by that person.

In addition, Kurlander says the alert includes the "fair-market value" measurement the industry was hoping for.

The fraud alert attempts to put to rest a long-running debate over the use of rental space in physician offices, otherwise known as "supply closets." Physicians and hospitals often keep limited supplies of durable medical equipment, prosthetics, orthotics and supplies on site for convenience and to facilitate patient discharge.

However, the OIG contends that excessive rental payments can be a ruse to disguise kickbacks from the suppliers to physician-landlords for referrals, and may violate the federal anti-kickback law.

According to the OIG, questionable features of suspect rental arrangements center on the following three primary areas:

- **Appropriateness of rental agreements.** The threshold inquiry when examining rental payments is whether payment is appropriate at all. Payments of "rent" for space that traditionally has been provided for free or for a nominal charge for the benefit of the physicians' patients. In general, rental payments for consignment closets in physicians' offices are suspect.
- **Rental amounts.** Rental amounts should be at fair-market value, fixed in advance, and not take into account, directly or indirectly, the volume or value of referrals or other business generated between the parties. Fair-market value rental payments should not exceed the amount paid for comparable property.
- **Time and space considerations.** Suppliers should only rent premises of a size and for a time that is reasonable and necessary for a commercially reasonable business purpose. The basis for any proration should be documented and updated as necessary.

To read the entire OIG Fraud Alert, go to http://www.hhs.gov/oig/frdalrt/index.htm. ■

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physician services between 1995 and 1998.

According to the settlement agreement, the university self-reported possible violations in June 1996, after an initial inquiry revealed that in some instances the physician may not have been present for each billed service. But health care attorney **William Sarraille** of the Washington, DC-based law firm Arent Fox says the university's attempt to police itself may have paid meager dividends. "Looking at this, it is hard to see what they really got for their voluntary disclosure and their commitment to compliance," he asserts.

"This is a case in which the government arrives at a False Claims Act settlement where there has been a voluntary disclosure," argues Sarraille. "I would say this is another example of what appears to be a disturbing trend."

"Unfortunately, the way the False Claims Act is written, a voluntary disclosure doesn't prevent a relator from filing a subsequent case," says Assistant U.S. Attorney **Linda Wawzenski**. "The only thing the statute gives someone who voluntarily discloses is a guarantee that the damages will not go any higher than double damages instead of treble damages under the statute."

According to Wawzenski, the only basis on which you can say that a whistle-blower cannot file a lawsuit against a defendant is if the relator is filing a lawsuit based on a public disclosure. "It is not as if the statute says that if you voluntarily disclose to the government, nobody can file a *qui tam* suit against you. I sympathize, but that is the way the statute is currently written."

Wawzenski does cite a recent case in the Seventh Circuit that may buck that trend. The decision in that case, *U.S. ex. Rel, Eunice Mathews v. Bank of Farmington,* suggests that under certain circumstances a voluntary disclosure may be considered a public disclosure, prohibiting a relator from filing a valid *qui tam* suit.

Under the terms of the settlement, the university agreed to pay the government $8,275,000 and an additional $2,625,000 to the state of Illinois. The whistle-blower in the case, Al Reppine, a former registered nurse and protocol research clinician at Weiss Hospital, which is affiliated with the University of Chicago Hospitals, will receive $1,850,000 for his role in the litigation.

Serraille also questioned the manner in which the settlement was disclosed. "This clearly is not the tact that had to be taken, and the press coverage is not going to be conducive to the institution's reputation and standing," he argues. "There are dozens, if not hundreds, of cases that never have a press release initiated." ■

GAO: Extent of Medicare fraud is uncertain

General Accounting Office (GAO) Comptroller David Walker told the House Budget Committee Feb. 16 that that the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) has no system in place to identify and measure fraud and abuse in the Medicare program. Walker placed much of the blame on the doorstep of the Health Care Financing Administration's (HCFA) Medicare contractors, which he says are plagued by financial management and information systems weaknesses. He added that HCFA lacks the authority to increase competition among contractors to enhance performance.

HHS Inspector General June Gibbs Brown did not disagree. In fact, she emphasized that HCFA's highly touted reduction in payment errors — from an estimated $23.2 billion in 1996 to $12.6 billion in 1998 — is not an accurate gauge of fraud. "While the error rate estimate may include some instances of fraud, it is a payment error estimate and not a fraud estimate," she told the committee. It may detect some fraud, but is not likely to detect sophisticated fraud such as falsification of documents and illegal kickbacks, she added.

"The very nature of fraud makes it very difficult to quantify," says OIG spokeswoman Alwyn Cassil. "An error rate is not a measure of fraud even though everybody tries to use it that way. But rather than putting resources into defining a problem that we all know exists, we want to focus on dealing with it."

Brown added that the OIG has several ongoing investigations into psychiatric services at 10 acute care hospitals and psychiatric hospitals in 10 different states, as well as ambulatory care settings and outpatient rehabilitation facilities. ■