AMERICAN HEALTH CONSULTANTS

COMPLIANCE HOTLINE™

THE NATION'S ESSENTIAL ALERT FOR HEALTH CARE COMPLIANCE OFFICERS

MONDAY
AUGUST 19, 2002

Final HIPAA privacy rule contains good news for providers

Nevertheless, experts say many hospitals still have significant work ahead of them

The Department of Health and Human Services (HHS) last week released final regulations implementing changes to the Health Information Portability and Accountability Act (HIPAA) privacy rule.

The news was mostly good for providers. "The final rule contains a few surprises," says **John Bentivoglio**, former chief privacy officer at the U.S. Department of Justice. However, the vast majority of changes were in the proposed rule issued last March, he says.

The Chicago-based American Hospital Association (AHA) applauded HHS for adopting the changes. "The final regulations retain strong protections for patients' medical privacy rights while eliminating some major barriers to timely and effective care," the association contends.

Most importantly, the final regulations adopt the proposal to allow written acknowledgment to substitute for written consent requirements and retain written consent as an option. The final rule also allows for the disclosure of "facially de-identified" data for health care operations and research pursuant to a data-use agreement, according to the AHA.

Bill Braithwaite of PriceWaterhouseCoopers in Washington, DC, says he was mildly surprised at how HHS handled the consent issue. "There was

*See **Final rule**, page 2*

Expert offers three keys to statistical challenges

Nobody argues the need for scientific statistical sampling and extrapolation in cases of overpayment determination. However, the government often falls short in making its case, says **Michael Intriligator**, PhD, economics professor at the University of California, Los Angeles. "There is no question you need scientific statistical sampling," asserts Intriligator, who has successfully challenged the sampling methodology used by the Centers for Medicare & Medicaid Services (CMS). "But it has to be done properly."

If it is not done properly, Intriligator says, it can be thrown out either at the fair-hearing level or

*See **Statistical challenges**, page 3*

Enforcement of privacy regulations still uncertain

Now that the Department of Health and Human Services (HHS) has released final privacy regulations for the Health Information Portability and Accountability Act (HIPAA), enforcement of the new rule is a major concern. "The scariest thing about the new rule is that in many instances, it may give hospitals and others a false sense of security," says **Eileen Boyd**, managing partner at KPMG in Washington, DC. Because hospitals are not required to have patients sign off regarding consent, she says many hospitals may overlook the fact that they lack necessary policies.

According to Boyd, many hospitals still lack sound policies and procedures regarding what information they will or will not give out. "For many, there will be a very false sense that they have won something here they have not won," says Boyd, a former senior attorney at HHS who helped draft much of the privacy regulations.

*See **Privacy enforcement**, page 3*

Final rule

Continued from page 1

a lot of controversy about it, and I would have expected them to compromise a little bit," he says. "Yet, they just adopted what they proposed."

The final rule also allows an additional year to incorporate the business associate requirements into existing written agreements that are not up for renewal and significantly simplifies the research authorization requirements.

The final rule also tightens the restrictions on marketing, says **Mary Grealy**, president of the Healthcare Leadership Council in Washington, DC. For example, she says it now is very clear that you cannot sell lists of names of patients to pharmaceutical companies.

Braithwaite says HHS did a credible job trying to draw "a difficult line" in this area. "The proposal was way off in one direction," he says. "Their final [rule] was closer to what providers wanted."

Research is another area where HHS made "some very sensible improvements," according to Grealy. For example, a proposal made during the Clinton administration would have required research organizations to remove 19 pieces of identifiable information. "If you were to remove all 19 pieces, the information was useless," she argues.

In the final rule, that list has been shortened considerably. Research institutions are not permitted to use "direct identifiers" such as name, Social Security number, address, e-mail address, or anything that can directly identify a person.

However, they can use items such as the date of admission to a hospital, date of birth, and zip code. "For people doing epidemiological studies, they can still detect patterns they need to detect," says Grealy.

AHA called on HHS to quickly release the security rule, which it says is needed for timely and seamless implementation of the new privacy rule. Now that the final privacy rule is published, Braithwaite says HHS officials working on the security rule can finish their harmonization to make sure the privacy and security regulations are completely compatible. "That means it probably cannot be published before October," he predicts.

Even with the relaxation of certain requirements, the final privacy rule will require sweeping operational changes, the AHA warns. "Now that the final rule has been put to bed, it will be a real race for many companies to comply with the April 14 deadline," Bentivoglio adds.

Because the final rule was subject to change, he says many companies opted to defer a variety of compliance activities, such as drafting agreements. "With the rule in place, companies are confronting the reality that they only have a few months to come into compliance," he says.

Braithwaite says the readiness of most providers depends on whether they have been looking for an excuse to delay their preparation. "Many hospitals and other providers are really strapped for resources," he says. "They have been squeezed pretty tight over the last decade, and they are looking for any excuse not to spend money because their bottom line is really hurting."

According to Braithwaite, who helped draft much of the privacy rule as a senior official at HHS, the final rule is not as onerous as many people believe.

"It is mostly a matter of drafting policies and procedures, writing and filing some documents, and changing some processes," he argues. "It is not that different from what they should already have been doing, although they may not have.

"Many providers may actually have many of the policies and procedures in place already," he adds. "They just have yet to bring them together in a coherent privacy and security plan." ■

Compliance Hotline™ is published every two weeks by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. *Compliance Hotline*™ is a trademark of American Health Consultants®.

SUBSCRIBER INFORMATION
Please call **(800) 688-2421** to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call **(404) 262-5536**. Our customer service hours are 8:30 a.m. to 6 p.m. EST.

Privacy enforcement

Continued from page 1

In terms of enforcement, **Mary Grealy**, president of the Healthcare Leadership Council in Washington, DC, says that, over the next 12 months, everyone who is affected by the regulation will have to work in collaboration. "I don't think HHS is going to be on a mad hunt for violations," she predicts. "But they want providers to comply."

Grealy says HHS is not likely to get bogged down by attempting to make sure that providers have everything in place by April 14, 2003. "I think they are going to go after the things that people care about rather than the minutia of the regulation," she says.

Former HHS official **Bill Braithwaite** takes a similar view. According to Braithwaite, the letter of the law is specific about HHS' enforcement on the civil side. "The law is quite specific about what the secretary can and cannot do," he explains. "Basically, you can't fine somebody unless you get to the point where they can comply."

"I don't expect a lot of civil fines under HIPAA," he adds. "However, I do expect HHS to investigate complaints." In some cases, he says, the agency will help people comply; and in the most egregious cases, it will refer cases to the Department of Justice for prosecution under the criminal penalties.

According to the Health Information Portability and Accountability Act (HIPAA) regulations, HHS is in charge of all enforcement apart from criminal penalties for breaches of privacy. The HHS' Office of Civil Rights has been designated within the agency to enforce the civil side of privacy.

According to Braithwaite, the assumption is that the Centers for Medicare & Medicaid Services (CMS) will be responsible for the rest of administrative simplification enforcement. "However, they have yet to come out with an enforcement rule that would say exactly how that will be done," he says.

HHS has indicated it plans to come out with an enforcement rule that will lay this out sometime before the first compliance date, says Braithwaite. "On the other hand, there is no requirement for them to do that," he says. "They could just play it by ear and pick up complaints and enforce in some ad hoc way." ■

Statistical challenges

Continued from page 1

more likely at the administrative law judge (ALJ) level. In other instances, this can occur at the Medicare Appeals Board level.

"Usually, you do lose at the fair-hearing level," says Intriligator. "But I have had a couple of cases where we actually won at the fair-hearing level." He says that can be accomplished through successful legal or statistical challenges.

According to Intriligator, whether to use a statistical challenge depends on the amount of money involved as well as some of the statistical results. He also notes that carriers and the ALJ increasingly are bringing in their own statistical experts.

Intriligator says there are three primary issues, which he calls "the big three," that health care attorneys should consider when deciding whether to challenge carriers and intermediaries:

- **Sample size.** According to Intriligator, sample size is the No. 1 issue. Frequently, he says the sample size of the claims selected is too small and inconsistent not only with generally accepted statistical principles but with CMS' own guidelines for a "basic sample size." In some instances, the number of claims selected can be less than a tenth of the number required, he says.
- **Documentation.** The second key area is documentation. Intriligator says the government must provide enough documentation to create an audit trail so the study can be replicated. He says all the authorities, statistical textbooks, and guides are very clear on this point.

"I find it very ironic that many times they will claim an overpayment based on the fact that there was not adequate documentation of the medical procedures," he argues. "Yet, when the carrier does the statistical exercise, they do not provide enough documentation."

Continued on page 4

♦ **Randomness of the sample.** To be statistically valid, the sample must be selected at random, with no biases or other distortions that could make it not "representative," says Intriligator. Sampling that specifically omits low-charge claims, for example, would not yield a reasonable sample, he says.

The coefficient of variation is a measure of the variability in the sample, Intriligator explains. If the variability is too high, it means the estimates are very imprecise and there is inaccuracy, he says. Likewise, if the coefficient is too high, the study is unacceptable.

Intriligator says one package that is widely used is the Health and Human Services' Office of the Inspector General's Office of Audit Services software package RAT-STATS. "This is actually a library of different computer routines, some of which I find perfectly acceptable," he says. "For example, their random number generator I find perfectly acceptable."

"The rest of it, I have some doubts about," he adds. Intriligator says the manual offers no information about what goes on inside the program. "It only tells you how to operate the program," he explains. "There is no information about what is inside that program."

Another area of possible error is improper stratification. "Stratification and the choice of strata is a very important issue," says Intriligator. This process divides the population into different subpopulations that are relatively homogeneous. For example, hospital services might be stratified into inpatient/outpatient or other categories, while physician services might be stratified by diagnostic categories, he explains.

Nevertheless, this is not always done. "If they did not use stratification with a heterogeneous population, the results are nonsense," he argues. "It is like adding apples and oranges." Conversely, some cases use stratification when it should not be used.

Outliers in the sample are another issue that should be looked at, says Intriligator. Sometimes the sample includes unrepresentative outliers that can bias the results, he explains.

"Any one of these issue areas or some combination of them could represent a basis for challenging the sampling/extrapolation," Intriligator concludes. It also is possible to challenge the qualifications and capabilities of those performing the study, he adds.

Note: Intriligator and Lester Perling, a health care attorney with Broad & Cassel in Tampa, FL, have co-authored a monograph on this subject published by the American Health Lawyers Association called *Statistical Sampling in the Medicare Program: Challenging Its Uses.* ■

OIG cites overpayments after consolidation

According to a report issued by the Health and Human Services' Office of Inspector General (OIG) Aug. 6, 15 hospitals that technically ceased to exist after consolidation with another hospital were paid for 1,118 discharges that should not have been billed to Medicare.

Katie McDermott, of the law firm Blank Rome in Philadelphia, says the OIG is highlighting a risk issue that was not immediately foreseen in the merger context. "It is a compliance issue, but it is not inherently a fraud and abuse issue," McDermott says. "Hospitals should be alert to making sure that once they have integrated merged entities, they are addressing any reimbursement issues that can arise."

Under Medicare rules, a consolidation of hospitals is considered a change of ownership. After a consolidation, only the surviving hospital is entitled to Medicare payments because it was the legal owner on the date patients were discharged.

The OIG identified overpayments of more than $4.5 million for six of the 15 hospitals and says it will make referrals to fiscal intermediaries for recovery. Intermediaries also have recovered nearly $300,000 related to two consolidations and have initiated recovery actions related to two additional consolidations. In addition, the Department of Justice has reached settlements totaling nearly $3.2 million related to five consolidations.

The Centers for Medicare & Medicaid Services (CMS) concurred with the OIG's recommendation to review current claim, cost report, audit, and change of ownership instructions to determine whether revisions or additions are necessary to clearly address proper claim filing and cost treatment when a change of ownership or consolidation occurs. ■