AMERICAN HEALTH CONSULTANTS

COMPLIANCE HOTLINE™

THE NATION'S ESSENTIAL ALERT FOR HEALTH CARE COMPLIANCE OFFICERS

MONDAY
DECEMBER 17, 2001

CMS puts one-year freeze on key provisions of Stark II

Health care attorneys say the move will prevent major restructuring by physicians and hospitals

The Centers for Medicare & Medicaid Services (CMS) has issued a new interim final rule that puts a one-year freeze on the so-called "set in advance" provision included in the first phase of the Stark II final regulation, which is scheduled to take effect next month.

"I think this is very significant," says **Sandy Teplitzky**, chair of the health care practice at Ober Kaler in Baltimore. Absent the freeze, he says, the "set in advance" provision could have required many group practices and virtually every faculty practice plan in teaching hospitals to restructure their physician compensation systems.

The interim regulation temporarily allows for arrangements involving all types of percentage compensation to qualify for protection under the Stark exceptions, assuming the other requirements of the exception are satisfied.

According to health care attorney **Robert Homchick** of Davis Wright, the "set in advance" requirement originally stated that percentage contracts based on an indeterminate sum would not meet the standard that is included in a number of exceptions, such as the personal service arrangement exception, the exception for rentals, and the academic medical center exception.

*See **Stark II**, page 2*

Maximize effectiveness through organization

One of the keys to maximizing the effectiveness of a compliance program is to maximize the different skill sets each team member brings to your process and function, says **Jane Conard**, senior counsel at Intermountain Healthcare (IHC) in Salt Lake City. That begins with effective internal organization, she says.

IHC is a nonprofit integrated health care delivery system with 22 hospitals predominantly located in Utah and Idaho. The systems has more than 100 physician clinics, managed care plans including more than 500,000 lives, and 23,000 employees.

Suzie Draper, compliance administrator at IHC,

*See **Effective organization**, page 4*

HIPAA survey reveals potential land mines

Ninety-three percent of health care providers responding to a Health Insurance Portability and Accountability Act (HIPAA) readiness survey released earlier this month by the Philadelphia-based Health Care Compliance Association (HCCA) have established a HIPAA task force, and 77% have designated a privacy officer. But behind those numbers are some ominous findings, warn several privacy experts.

One area of concern is readiness, says **Eileen Boyd**, managing partner at KPMG in Washington, DC.

She notes that 67% of respondents report they have not developed cost estimates for privacy, security, and transaction requirements. "That surprised me," she says. "Especially since we are entering a new year of budgeting."

Anthony Boswell, chief compliance officer for Laidlaw in Arlington, TX, finds that less surprising,

*See **HIPAA survey**, page 3*

Stark II

Continued from page 1

Homchick says that would have meant that a percentage of charges, percentage of collections, and percentage of a bonus pool set up by a faculty practice plan would be prohibited if providers wanted to fit within those specific exceptions.

"It was interesting that was the one thing they chose to fix at the present time," says **Linda Baumann**, a health care attorney with Reed Smith in Washington, DC. She adds that while additional changes in the regulation are likely at a later point, this provision in particular would have caused major disruptions.

According to Baumann, while the first phase of the Stark II regulations allowed certain limited types of percentage compensation arrangements to qualify for the Stark exceptions, few providers have those types of agreements. "The ones they were going to disallow were the arrangement everybody had," she explains. "Now those are OK for another year."

Not everybody is entirely optimistic about the change, however. "I really think this is being blown a bit out of proportion," argues attorney **Alice Gosfield**, president of Gosfield and Associates in Philadelphia. While she says CMS's latest action represents "a useful, positive, and more practical development," she also warns that it is applicable only to Stark and not to the anti-kickback statute.

"The anti-kickback statute has safe harbors, and if you don't conform to a safe harbor, it does not mean that you are violating the statute; it means that you are in a prosecutorial discretion frame of reference," she asserts. "It is not relevant to everything you have to worry about under Stark. It is not relevant to all contracts under Stark. It is not even relevant to all use contracts under Stark."

According to the regulation, the delay is intended to prevent hospitals, academic medical centers, and others from having to renegotiate thousands of physician contracts and give CMS time to reconsider the matter. But how many providers can benefit from the change is unclear.

Because the regulation has been implemented in phases, Homchick says some providers were somewhat on hold. "I think that is a false sense of security because Phase I is going to be effective, and it will be a basis upon which enforcement actions could occur," he says.

Gosfield says that contracts are quite variable, and a lot depends on whether providers have a "change of law" provision in their contracts. Many contracts have those clauses, she adds, noting that they usually are written to accommodate a change in law that would make a certain practice illegal. "This is the obverse of that," she explains.

Whether CMS will make the temporary freeze permanent is uncertain. "My guess is that, in Phase II, they will back off this requirement and make some further clarifications," says Homchick. But he doesn't rule out the possibility that CMS could decide to stand by the requirement and give providers a set period to become compliant.

The final regulation for the remaining portion of the Stark II regulation will cover considerable ground, Baumann says. "You still have many exceptions for compensation or ownership arrangements, not to mention the whole Medicaid issue that has not been addressed yet in final regulations," she says. ■

Editor's Note: This issue of *Compliance Hotline* marks our 26th and last issue of 2001. Because of the holidays, our next issue will be released on Monday, Jan. 7, 2002.

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.

HIPAA survey

Continued from page 1

however. "We have not done that yet either, because we are doing assessments at a few key locations," he reports. "You really have to assess what you are going to do before you can figure out what it is going to cost you."

Boyd says the other finding that concerned her was that 73% had not established security levels for employees, medical staff, and business associates. "I can't imagine that in any hospital where there is a computer that you would leave that computer open or give somebody your password," she says.

According to the survey, only 26% of respondents reporting on security aspects of HIPAA indicate that they had performed a "penetration analysis" to determine where and how security breaches may occur, and only 19% of respondendents have determined how system security will certify compliance.

When it comes to planning issues, there is a fairly high degree of compliance, says health care attorney **Brenda Strama** of the law firm Vinson & Elkins in Houston, which helped conduct the study. But when it comes to implementation, most providers are not very far along on many of the more difficult issues, she adds.

Boswell says that providers are largely in the assessment phase. But he adds that part of that assessment should include "pre-implementation" steps. "Actual implementation is a bit premature with certain aspects, such as privacy, but not with transaction and code sets," he says.

Strama says her other major concern is that nobody seems very prepared for standards, transactions, and code sets. While that area currently is scheduled to be implemented first in October 2002, Strama says it is the area where providers are lagging the most. It now appears that Congress may delay this implementation date for one year, however.

Fifty-nine percent of those responding to the survey have identified all transaction standards and code sets, but only 32% have gauged the preparedness of trading partners, and only 28% have developed a system for ongoing maintenance of standards transactions and code sets.

While the provider community is split over whether to support further delays, Boswell says he likes the idea of pushing everything back and letting providers focus on privacy. "That is a big piece and the one that is the most important in gaining patient and customer trust," he says. "They all go hand-in-hand, but privacy is the linchpin."

Like Boyd, Strama says she also is concerned providers are holding back on the security portion. On one hand, she says that is understandable since the final regulation is not expected until next month.

On the other hand, that requirement is going to take a long time to comply with, and there is a lot that providers can do to become compliant, she argues.

Here are some of the survey's other findings:

- 64% of respondents have reviewed employee screening and background checking practices;
- 81% have determined the organization's designation as a covered entity;
- 60% report that a security officer has been designated;
- 54% report that the privacy and security responsibilities have been assigned to one individual;
- 40% have developed organizational structures that delineate responsibilities for privacy and security;
- 33% have developed cost estimates for privacy, security, and transaction requirements;
- 49% note policies have been developed related to discipline for breach-of-privacy principles and breaches of security;
- 41% have developed a grievance policy to address complaints about privacy and breaches of confidentiality;
- 53% have developed policies related to patient access to records.

However, 78% indicate they have not developed access to "minimum necessary" information policies, and 80% have yet to develop policies addressing the potential exposure of protected health information through viewing, paging, or other operational activities.

The complete survey is available at www.hcca-info.org. ■

Effective organization

Continued from page 1

says that when the IHC Board of Directors established a compliance department several years ago, it was intent on vesting one person with sufficient "scope of influence" to bring about real change within the organization. That person, who quickly decided to hire a compliance administrator to operationalize the program, still chairs the compliance committee, which includes internal audit, legal, and clinical support.

According to Draper, another important part of IHC's organizational structure is its advisory committee, which includes regional vice presidents and clinical vice presidents. "Whenever we have an enterprisewide initiative, it is important that we bring them on board," she says.

The compliance team is divided into compliance subcommittees, which are further divided by legal subject matter. "The areas where we found the most success are those where we have our facility or operations coordinators working closely with compliance workgroups," says Draper. Conard adds that human resources, managed care, environmental issues, and information security all are part of the comprehensive compliance program as well.

Another key to success is to make sure that every area has clear accountability. Facility and operations have line accountability, Draper says. "We also emphasize that is the first line of communication," she adds. "We don't want to have anyone feel they need to circumvent those organizational structures and go to the hotline or central compliance if they can have those issues solved first within the organization or operation."

Those areas also are accountable for training. "Because we have different types of operations, they are accountable for different risk assessments," Draper reports. For example, the risks facing the children's hospital are very different from some of the full-payer acute facilities. Likewise, the home care operation has 10 different agencies. "Each of these facilities must be looking at the different risks and making site-specific risk assessments," she says.

In addition, IHC has more than 30 workgroups that are focused on various functional areas. "They are the ones looking at the OIG guidance specifically written for the different areas," explains Draper. "We also have found that this is an important area to link compliance to quality."

Draper says it also is important to link quality in clinical programs with compliance. That begins with documentation and understanding conditions of participation. "I can't stress enough how essential it is to have the clinician on board," she asserts.

In addition to monitoring operations and discovering and logging compliance issues, hospitals must execute corrective action plans appropriately, Draper says. That means that the staff that oversee employees and budgets must make sure these processes have been implemented. ■

OIG semiannual report holds few surprises

The Health and Human Services (HHS) Office of Inspector General's (OIG) Semiannual Report to Congress released Dec. 7 holds few surprises, according to several former OIG staff and other OIG watchers. Many familiar themes, including quality of care, payment for pharmaceuticals, and transfers and discharges are highlighted in the report. On the whole, it appears to be "less intrusive" then many earlier reports, says former OIG senior counsel **Eileen Boyd**, now managing partner at KPMG in Washington, DC. She says that may reflect the early influence of HHS Inspector General Janet Rehnquist, who assumed the post last summer.

Former OIG attorney **Julie Kass**, now a health care attorney with the Baltimore-based Ober Kaler, says the report held few surprises. The type of providers being scrutinized remains "fairly stable," she says. That list includes hospitals, skilled nursing facilities, home health agencies, and durable medical equipment suppliers, and prescription drugs companies.

Several major hospital initiatives have dropped off the list of items the OIG is reporting, including the DRG window project and outpatient lab unbundling. But Kass notes that the Physicians at Teaching Hospitals, PPS transfer, and pneumonia upcoding initiatives still appear to be active. ■