AMERICAN HEALTH CONSULTANTS®

COMPLIANCE HOTLINE™

THE NATION'S ESSENTIAL ALERT FOR HEALTH CARE COMPLIANCE OFFICERS

TUESDAY
JANUARY 16, 2001

HCFA's implementation of Stark II raises key concerns

HCFA splits final self-referral rule into two parts and delays the effective date by one year

The emerging consensus on the final Stark II regulations released Jan. 4 by the Health Care Financing Administration (HCFA) is that the agency came up with a good regulation for a bad law. "They have definitely made it a more manageable rule," asserts **John Steiner**, director of corporate compliance at the Cleveland Clinic Foundation. But other veteran observers voice concern about how the final rule is going to be implemented.

Providers have until Jan. 4, 2002, to comply with the portion of the final rule just published. The agency deferred the release of part of the regulation, but put no timetable on its completion.

"We don't have the whole puzzle yet," says health care attorney **Gregg Wallender** of Hall Render in Indianapolis. "That makes it difficult to fully assess." He adds that, while he understands why a delay in the effective date for new requirements was warranted, it would have made sense to immediately broaden some of the requirements, such as medical staff incidental benefits. "Some of these things should be effective immediately, and we would have some very clear guidance on the books," he argues.

Most observers also were surprised by the agency's decision to bifurcate the release of the final rule. Health care attorney **Robert Homchick** of Seattle-based Davis Wright, says his gut reaction is that the statute does not really

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

Prepare for patient privacy by starting with the basics

Health care providers face a steep learning curve before they master the medical record confidentiality regulations that go into effect two years from now. Health care attorney and health information expert **Dan Mulholland** of Pittsburgh-based Horty Springer says that initial efforts to consolidate a notice to patients about their privacy rights were futile. "We started trying to draft a notice of privacy policies following the regulations, and we quit after about five pages of small print."

According to **Alan Steinberg**, also of Horty Springer, that's why providers must begin acclimating themselves to the central concepts included in

*See **Patient privacy**, page 3*

Final regulations include significant changes

Health care attorneys who have spent the last two weeks pouring through the fine print of the final Stark II regulations are finding numerous changes and many improvements in the proposed rule.

Among the most important changes in the final rule are the use of CPT codes for some of the designated health services and the broadening of the group practice unified standard requirement from the proposed definition, says health care attorney **Gregg Wallender** of Hall Render in Indianapolis.

On the flip side, he says the Health Care Financing Administration (HCFA) narrowed the ability of health care entities to engage in certain nonabusive percentage arrangements. He says that some of the special rules on compensation, such as narrowing what type of percentage arrangements are allowable, will make some reasonable business arrangements more complex and others impossible.

*See **Final regulations**, page 2*

Stark II

Continued from page 1

lend itself to dealing with certain sections and definitions independent of the other exceptions and provisions.

That doesn't mean the portion of the rule already released is likely to change noticeably following the comment period. In fact, Steiner points out that it is uncommon for HCFA to make any major changes in a final rule. "Barring grammatical errors that affect the actual meaning of the regulation, we are probably going to see this final rule as is," he predicts.

Bill Vaughn, a senior aide to Rep. Pete Stark (D-CA), the law's author, says it is too early to know whether Congress will attempt to further amend the self-referral statutes. But he argues that HCFA "bent over backwards" to respond to the comments it received. "If this doesn't please the critics, nothing will," asserts Vaughn.

Standing on the other side of that argument is the just-named head of the House Ways and Means Committee Rep. Bill Thomas (R-CA), who already has introduced legislation to strip the compensation portion of Stark II in its entirety.

While acknowledging that Thomas is a "very effective legislator," Vaughn says there is not much interest in this issue in the Senate, which is evenly divided between the two parties.

Moreover, self-referral is a notoriously difficult issue to lobby Congress on, Steiner says. He points to the extraordinary effort it took to educate legislators about self-referral when he was counsel at the Chicago-based American Hospital Association. In a busy tax-writing season, he predicts few congressional staffers are going to have much appetite to learn the nuances of Stark.

What's unknown is how vigorously the Justice Department under the incoming Bush administration will be in prosecuting potential violations. Vaughn says Justice recently notified Stark's office that 50 cases of potential Stark violations were under investigation. Recent predictions also have suggested that the area of self-referral will become ripe for whistle-blowers.

Steiner says that hospitals thinking about potential scenarios that may implicate Stark should consider the evolution of the law itself, which started with clinical laboratory services and then was expanded to include diagnostic services.

"If you are trying to structure priorities, it seems logical to me that you are talking about the home health items, which had [an early] effective date," he says. "Then you should look at clinical lab and diagnostic imaging, just to get something started." ■

Final regulations

Continued from page 1

Wallender also points out that HCFA has yet to promulgate regulations for two major categories of exceptions. The statute includes three categories of exceptions, he notes. The one pertaining to both ownership and compensation was covered in the published regulation. But the ones pertaining to ownership and investment interest and compensation arrangements were not, although new compensation arrangement exceptions were added.

"We still have two major categories of exceptions outstanding," he says. "But for the most part, many of those are pretty self-explanatory, so I think we will get by." On the other hand, a few significant areas are not in final form yet, such as physician employment, which probably is the most common occurrence.

Wallender says the safest way for providers to proceed is to go by the literal terms of the statute. "We still have HCFA's commentary from the proposed regulations to guide us in those other aspects as well as the final regulations from Stark I," he adds. "Those three pieces of information

(Continued on page 3)

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 6:00 p.m. EST.

are our best resources."

According to health care attorney **Robert Homchick** of Seattle-based Davis Wright, HCFA attempted to clarify the definitions for designated health services with some success. The agency also articulated a test for determining whether an indirect financial relationship will trigger the referral prohibition.

Likewise, HCFA also attempted to be more flexible in how group practices organize themselves in the in-office ancillary service exception, he says. But further study is required before it is clear whether the lines that have been drawn are practical.

HCFA also refined the definition of referral and excluded services originally performed by the referring physician. Homchick says that is important in the context of determining whether group practice compensation and other compensation are based on the volume and value of referrals.

The agency also added a new exception for academic medical centers that addresses the compensation of faculty in that context, as well as a risk-sharing exception for commercial and employer-sponsored managed care plans.

John Steiner, director of corporate compliance at the Cleveland Clinic Foundation, says the refinements in the final regulation add badly needed flexibility to the exceptions, particularly for compensation arrangements.

He says that is especially true since existing federal fraud and abuse statutes have common elements. In the past, when providers scrutinized Stark exceptions and safe harbor regulations, a mismatch in requirements often emerged. "Now they are more compatible with each other and much easier to interpret and apply consistently," Steiner contends. "That is very important."

According to health care attorney **Charles Oppenheim** of Los Angeles-based Akin Gump, the final rule includes good news for medical groups because it will make it somewhat easier to deal with certain requirements, such as supervision for ancillary services. He also applauds an exception for risk-sharing arrangements that could prove beneficial for providers, as well as the increased clarity for indirect compensation arrangements.

There is ample room to criticize many of the specifics, adds Oppenheim. "But there would be no way to write a rule that would make everybody happy," he concludes. "They have tried to balance competing interests, and I think they did a decent job." ■

Patient privacy

Continued from page 1

the new regulation mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as quickly as possible. He says the basic rule governing health information — technically known as "rules for use and disclosure" — is that providers must obtain the patient's consent to use and disclose protected health information for treatment purposes, payment purposes, and internal operations.

It actually goes even goes further, Mulholland says. Unlike the proposed regulation, which did not anticipate that providers would have to obtain specific consent in order to use medical records within the hospital, the final regulations mandate that consent be obtained. "The basic rule is that you can't do anything with this [information] unless they say you can or they say you have to," he explains.

Here are six core concepts Steinberg says providers should pay close attention to as they familiarize themselves with the new privacy mandates:

1. Patients always have rights over protected health information and always have access to that information. The only time providers can use or disclose that information is with the consent of the individual for the purposes of treatment, payment, or internal operations.
2. That does not mean the patient owns the information, says Steinberg. On the contrary, almost every state law on the books says the provider owns the health information. "That stays the same, even though the individual has to consent for usage and further disclosure of it."
3. There are some very specific instances where the consent of the individual is not required. They include cases in which emergency treatment is required and when disclosure is to a family member involved in the patient's care. Consent also is not required when providers are required by law to treat patients or have an indirect treatment

(Continued on page 4)

relationship with the patient or where an effort was made but substantial barriers exist.

4. Patient "consent" is distinct from patient "authorization." In short, patient authorization is required whenever records are going to be released for any purpose apart from treatment, payment, or health care operations.

"You can transmit the information to a health insurance company in order to get paid, as long as you have that basic consent," explains Mulholland. "Anything else needs an authorization." Where possible, he says, it helps to distinguish these two critical responsibilities.

5. The individual has the right to at least try to have the covered entity agree to minimize disclosure of protected health information. "You have to pay attention to that," warns Steinberg.

6. HIPAA includes a long laundry list of specific situations where providers can release records without patient authorization.

"It is a little quirky at first to think that someone has to consent for you to use this material all along," argues Steinberg. But he points out that the regulations also say that if patients refuse to give their consent, providers have the right to refuse admission and treatment. Likewise, health plans can deny enrollment if routine consent for treatment, payment or operations purposes is refused.

"That consent does not have to be separate from any other consent," says Mulholland. "You can have it on the same admissions form as long as it is clearly delineated as a separate consent on that form and signed separately." ■

HHS eyes further anti-fraud gains through HIPAA

The Department of Health and Human Services (HHS) attributes the "remarkable progress" it has made in rooting out health care fraud and abuse to the landmark Health Insurance Portability and Accountability Act of 1996 (HIPAA). It also notes in its semiannual report that the seven-year Health Care Fraud and Abuse Control Program established by HIPAA is only at its midpoint.

"With the number of HHS OIG [Office of Inspector General] civil actions, criminal prosecutions, and exclusions on the rise, as evidenced by the semiannual report, the industry should see this as a clear sign that the federal government is not going to let up on its efforts to combat fraud and abuse in the health care system," says **Richard Kusserow**, president & CEO of Strategic Management Systems in Alexandria, VA.

In the last four fiscal years under HIPAA, HHS reports overall savings of more than $47.3 billion, with Medicare and Medicaid accounting for more than 98% of the total savings.

For FY 2000, the OIG reports savings of $15.62 billion with the lion's share coming from implemented recommendations. About $1.232 billion is attributed to investigative receivables and the remaining $142 million to audit disallowances.

For the fiscal year, the OIG reports 3,350 exclusions of individuals and entities, up from 2,976 the year before. The OIG also reports a slight increase in the overall number of criminal prosecutions of individuals or entities that engaged in crimes against department programs, 414 (compared to 401 in FY 1999) as well as 357 civil actions.

There will continue to be increased resources from HIPAA through FY 2003. "What this shows is that when you pour more resources into a problem, you are going to get more enforcement activity, convictions, and exclusions," says **John Bentivoglio** of Arnold and Porter in Washington, DC. "What the industry has faced so far is merely going to increase as more and more resources are devoted to this problem." ■

OIG approves charitable donation to EMS

In a new advisory opinion, the Department of Health and Human Services Office of Inspector General (OIG) approved a proposed charitable donation of up to $5,000 from a hospital to a volunteer emergency medical services provider to pay for new equipment and paramedic training.

According to the OIG, a monetary donation by a hospital to a local ambulance company fits the meaning of remuneration for purposes of the anti-kickback statute if the intent is to induce referrals. But the OIG determined that it would not impose sanctions in this case because the proposed donation presents minimal risk of abuse, but significant benefit to the community. ■