AMERICAN HEALTH CONSULTANTS

# COMPLIANCE HOTLINE™

THE NATION'S ESSENTIAL ALERT FOR HEALTH CARE COMPLIANCE OFFICERS

MONDAY
DECEMBER 3, 2001


## HHS IG unveils new CIA claims review procedures

*OIG gets high marks for loosening the reigns on corporate integrity agreements*

In an open letter to health care providers, Health and Human Services (HHS) Inspector General (IG) Janet Rehnquist offered specific criteria providers can use to avoid corporate integrity agreements (CIA), the new bane of federal health care fraud enforcement.

"This is definitely consistent with the trends that we have been seeing," says **Arthur Di Dio**, a health care attorney with Arent Fox in Washington, DC. "There are no 'gimmes' in these new claims review procedures," he says, "but they go a significant way in making CIA requirements much more reasonable for providers."

Rehnquist says the Office of Inspector General (OIG) recognizes that in certain cases it may be appropriate to release the OIG's administrative exclusion authorities without a CIA. Her Nov. 20 letter directs OIG staff to consider eight criteria — ranging from whether the provider self-disclosed the alleged misconduct to how long ago the conduct occurred — to guide that determination as well as the substance of those agreements.

The IG also is modifying the provisions of CIAs that address billing reviews and the use of independent review organizations. Specifically, the CIA billing review requirements will mandate the use of a full statistically valid random sample only

*See **Integrity agreements**, page 2*

## Assessment, measurement take center stage

The Health and Human Services (HHS) Office of Inspector General's recent initiative regarding corporate integrity agreements (CIA) once again underlines the need for providers to adequately demonstrate the effectiveness of the compliance programs. "Effectiveness equals assessments," says **Deborah Joslyn**, a senior manager with Ernst & Young in Iselyn, NJ. "Effectiveness equals measurement."

According to Joslyn, the programs that work are ones that use control reviews almost religiously, take the audit process very seriously, and are always looking for new ways to communicate.

*See **Assessing effectiveness**, page 4*

## OIG widens door for ASC hospital agreements

The Health and Human Services' Office of Inspector General (OIG) recently approved two proposed ventures involving ambulatory surgery centers (ASC) that health care attorneys say increase the flexibility hospitals have in this area.

The first advisory approves an existing ASC joint venture between a hospital-affiliated entity and an entity owned indirectly by five ophthalmologists, and the execution of three related ancillary agreements.

"This is a very good opinion because it is a sophisticated transaction with management agreements and facility support agreements," says **Katie McDermott**, a health care attorney with Philadelphia-based Blank Rome. "It very much reflects real-world health care operations, and the OIG did a very good job of sorting through the sophistication of the transaction and dealing with many of the complicated issues."

*See **Surgery centers**, page 3*

# Integrity agreements

*Continued from page 1*

if the initial claims review, otherwise known as a discovery sample, identifies an unacceptably high error rate. The OIG will use seven specific measures to make this determination.

The OIG's latest step is a continuation of a trend that started with the former IG's open letter of March 2000, which signaled for the first time that settlements would not always require CIAs. Only this time the IG lays out specific factors that providers should point out when they negotiate settlements. "They also leave it open that other factors might also be relevant," notes health care attorney **Jesse Witten** of Jones Day in Washington, DC.

Some factors seem more important than others, adds Witten, such as whether a provider has a sound compliance program and whether the matter came to the government's attention as a result of a self-disclosure. "Those are two items that go to a provider's state of mind and also are two things that providers can do something about," he asserts.

"In some cases, one factor might tip the scale in one direction or another," says Witten. For example, if the issue in question occurred long ago or very little money is at stake, those facts should be determinative even if the provider is weak in the other seven areas.

Di Dio says the most significant change is the creation of the financial error-rate threshold of 5%. He says this shows the OIG has listened to provider concerns regarding the financial impact of CIAs and their onerous requirements.

On the other hand, 5% is a fairly small threshold. "That means you get it right 95% of the time, and that is no easy task for any provider," he asserts. "They are definitely trying to maintain an enforcement flavor while making an attempt to reach out to providers."

While Di Dio takes a favorable view of the IG's overall effort, he also notes that the letter contains some "wishy-washy" language. For example, the OIG indicates that providers may use discovery samples as probe samples but only "in the OIG's discretion under certain circumstances."

The OIG makes it clear that it reserves the right to not apply these new claims review procedures to existing CIAs, Di Dio says. "I wish they would have been a little bit more clear in informing the health care community, particularly those who are party to existing CIAs, exactly how these claims review procedures can be applied to their existing CIAs and possibly used to modify those CIAs."

**Deborah Joslyn**, a senior manager with Ernst & Young in Iselyn, NJ, has other concerns. She says that while the industry has witnessed a decline in fraud and abuse, providers should not view the seven elements as perfunctory or assume the OIG is concerned only with billing audits.

"I think that misses the forest for the trees," she warns. "The reason providers get into trouble is typically due to poor controls." To the extent that some of those controls are eliminated, providers will wind up back in trouble, she cautions. ■

# New HHS CIA claims review procedures

Here are the seven items outlined by the Health and Human Services' (HHS) Inspector General designed to gauge the need for corporate integrity agreements (CIA):

**1.** Discovery sample of 50 randomly selected paid claims from each relevant universe of claims. The internal review organization (IRO) or internal audit staff will conduct the discovery sample, depending on circumstances and terms of the CIA.

*(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 p.m. EST.



**2.** Random OIG validations of a small percentage of CIA providers' discovery samples.

**3.** If the net financial error rate of discovery sample is below 5% (the reportable error rate), the provider is not required to do any further audit work under the CIA for that year. Results are reported to OIG, and any identified overpayments are refunded in accordance with payer policies.

**4.** If the financial error rate attributable to net overpayments is 5% or more than the reimbursement received for all the sampled claims, the provider must engage an IRO to conduct a statisically valid random sample (SVRS) for that same time period.

The provider may use the discovery sample as its probe sample. In the OIG's discretion, under certain circumstances, the OIG may allow the provider to internally conduct the review without an IRO.

**5.** The provider must repay identified overpayments in the sample in accordance with payer policies.

**6.** Concurrent with the SVRS, the provider will conduct a systems review related to the errors identified in the discovery sample.

**7.** The OIG may formally refer the results of the SVRS and systems review to the Medicare contractor for appropriate follow-up by CMS and its contractors.

Here are the criteria the HHS Inspector General will use to gauge the need for CIAs:

**1**. Whether the provider self-disclosed the alleged misconduct;

**2.** The monetary damage to the federal health care programs;

**3.** Whether the case involves successor liability;

**4.** Whether the provider still is participating in the federal health care programs or in the line of business that gave rise to the fraudulent conduct;

**5.** Whether the alleged conduct is capable of repetition;

**6.** The age of the conduct;

**7.** Whether the provider has an effective compliance program and would agree to limited compliance or integrity measures and would annually certify such compliance to the OIG;

**8.** Other circumstances, as appropriate. ■

# Surgery centers

*Continued from page 1*

The catch is that hospitals are not supposed to be a referral source, McDermott says. But in this case, the OIG read significant flexibility into a hospital's participation in ASCs on the basis that hospitals must be competitive with physician-based ASCs.

"They clearly are reading this, at least from the hospital perspective, in a flexible way that will allow for these relationships to develop and not taking a rigid extreme position in terms of reading those particular safe harbors," she says.

"I thought they were taking a hard look and trying to be a little more creative," agrees **Bob Homchick**, a partner with the law firm Davis Wright in Seattle. He notes there is a policy to encourage the use of ASCs in general because it is a less expensive way of delivering services than in the hospital.

Homchick says that is true regardless of what sector of the health care community has a piece of the action because it is viewed as a cost control. "People have tried to make the analogy to dialysis centers and other freestanding imaging centers," he says. "But I have heard from the regulators that they consider ASCs to be unique."

In some ways, that policy is encouraging, Homchick says. "On the other hand, if you are going to apply the logic of joint ownership to ASCs, why doesn't it apply in all of these other contexts? There is a little sleight of hand here."

The second opinion approved a medical center's proposed acquisition of an ownership interest in an operating ambulatory surgical center that is currently owned by a group of gastroenterologists.

McDermott says the recent opinions reflect an important trend under way in the OIG. "We are getting some pretty favorable guidance on some of these health care relationships in terms of how the OIG would view such an arrangement," she says. "That is becoming increasingly helpful in analyzing compliance and risk issues."

She says that in some of the earlier opinions there was a fear to say too much. "These ASC advisories are particularly useful," she says.

*(Continued on page 4)*

**Al Shays**, a health care attorney in Sonnenschein Nath's Washington, DC office, says that, unlike the ASC advisories, the OIG's two advisory opinions released Nov. 21 on hospice services break little new ground.

In one advisory, the OIG approved a hospital's proposed donation of free office space to an entity that provides free end-of-life services to patients with terminal illnesses.

However, it gave a "thumbs-down" to a payment arrangement between a Medicare-certified hospice and certain nursing facilities. At question were services provided to residents of such facilities who are eligible both for Medicaid and Medicare hospice benefits.

The OIG said it could not issue a favorable opinion because the requester failed to provide the agency with sufficient information. "That rarely happens," notes Shays.

According to Shays, providers typically have the opportunity to withdraw their request if the OIG suggests they will issue a negative opinion. In fact, most opinions now are negotiated. "There is a lot of give and take," says Shays. "They often point out concerns and ask for additional safeguards, but it must be remembered that providers are negotiating with the party that carries all of the negotiating leverage." ■

# Assessing effectiveness

*Continued from page 1*

"Those are the best programs," she argues. "If providers think a reactive audit will suffice, I think they are wrong."

Doing a lot of hardcore chart audits is valuable, but looking at the processes from the front line is equally important in order to avoid systemic issues.

Joslyn says the best way to measure the effectiveness of a compliance program is by addressing issues not through the hotline but at "the local level." She says the question to ask is whether people are participating in risk assessments at the local level, meaning that a manager assembles his or staff to evaluate what is working and what is not and making changes.

Determining who the primary audience should demonstrate effectiveness to is another challenge. "Our audience is the OIG because we have a mandatory CIA," says **Nancy Milner**, chief compliance officer at Eisenhower Medical Center (EMC) in Rancho Mirage, CA. "Everybody else is a minor player in all of this."

EMC has performed external and internal audits as well, she reports. But audits are not always the best tool in demonstrating effectiveness to the OIG, she adds. "We can audit all we want, but we can't get resolution unless our staff understand what we are talking about," she asserts.

In the first year of the CIA, the most vigorous audit was concerned with making sure that everybody had been trained, she says. One of the ways EMC accomplished that was through training surveys with its staff to determine if the education worked. "We audit so many different aspects of billing," she explains. "But we also audit compliance with how many people have signed the agreement and how many understand what a code of conduct is."

**Al Josephs**, director of corporate compliance at Hillcrest Health System in Waco, TX, says the most critical challenge in terms of measuring effectiveness is learning how to make it a part of an organization's culture. "You can perform education, but the real challenge is to keep it an exciting and viable part of the organization."

Josephs says the other challenge is integrating effectiveness measures into the overall ongoing operations of the organization. "We are hearing more about quality issues in nursing homes, and I can't help but think that will move to acute-care hospitals eventually," he asserts.

That makes it important for compliance officers to remain actively involved in the ongoing operations of the facility and coordinate what they do with other parts of the organization, such as quality management and quality improvement.

The next leap forward in this area may come through some form of standardization. Earlier this year, the Philadelphia-based Health Care Compliance Association initiated a collaborative effort to seek a measurable health care compliance program effectiveness standard. The initiative tasks a coalition of stakeholders with evaluating the results of an empirical study of compliance program effectiveness. ■