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OIG shifts gears to promote self-disclosure

IG's open letter says feds will soften corporate integrity agreements for cooperative providers

In an apparent effort to entice more health care providers to self-disclose incidents of fraud and abuse, the Department of Health and Human Services' Office of Inspector General (OIG) announced March 9 that it would soften the corporate integrity agreements (CIAs) it imposes on providers that volunteer incriminating information.

HHS Inspector General June Gibbs Brown revealed the policy shift in an open letter to providers last Thursday. The decision marks a significant move away from the increasing scope CIAs had started to assume. To date, more than 430 health care providers have entered into CIAs, whose increasingly onerous requirements have begun to raise the ire of providers.

The OIG says more than 70 providers have self-disclosed potentially abusive conduct. While that total does mark a notable uptick in the number of self-disclosures since Brown implemented the program two years ago, it remains a modest number.

When False Claims Act liability results from a disclosure, the OIG says it will now be "more flexible" in considering the terms of a CIA. "In general, we grant more deference to the existing compliance measures of a self-disclosing provider, even if those measures differ from what we might otherwise require in a CIA," Brown said.

In cases where the provider's own audits detected the disclosed problem, the OIG may consider alternatives to the CIA's auditing provisions and

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DOJ targets managed care and nursing homes

The U.S. Department of Justice's (DOJ) anti-fraud agenda will largely be driven by whistleblowers, DOJ's Special Counsel for Health Care Fraud, **John Bentivoglio**, reported at the national Health Care Compliance Association conference in Washington, DC, on March 9.

Bentivoglio cited three DOJ priorities in the health care arena — managed care, nursing homes, and prescription drugs.

Here is a rundown of DOJ's new enforcement agenda for these areas:

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Lawmaker seeks to open data bank to public scrutiny

Doctors and hospitals have much to fear if Rep. Tom Bliley (R-VA), chairman of the powerful House Commerce Committee, manages to bulldog his plan to open up the National Practitioner Data Bank (NPDB) to the public. Fortunately for health care providers, Bliley's idea is likely to be watered down considerably.

Bliley's scheme to open the NPDB was the subject of a contentious hearing before the House Commerce Oversight and Investigations Subcommittee March 1 that pitted Republicans against Democrats, Republicans against Republicans, and health care providers staunchly against the notion of making the data bank accessible to consumers.

Bliley contended that opening the NPDB is a matter of public safety. "It is unconscionable that consumers have more comparative information about the used car they purchase or the snack foods they eat than the doctors in whose care they

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Policy shift

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permit a self-disclosing provider to perform some or all of the billing audits itself, rather than require the retention of an independent review organization for each year of the CIA.

In addition, says OIG Associate Inspector for Legal Affairs **Lew Morris**, the OIG may narrow the scope and focus of the claims review to the areas found to be out of compliance. Alternatively, it may allow other audit methodologies in lieu of the statistical sampling methodology that is generally required.

Morris emphasizes that, to take advantage of the new policy, providers must have an effective compliance plan in place and self-disclose the potential problem.

"If the self-disclosing provider has demonstrated that its compliance program is effective and agrees to maintain its compliance program as part of the False Claims Act settlement, the OIG … may not even require a CIA," Brown asserted. "In those cases where, in our judgment, it is necessary to require the self-disclosing provider to enter into a CIA, the provider may need to make only limited changes to its existing policies and procedures to meet most of the requirements of the CIA."

Morris says the OIG wants effective CIAs that don't "break the bank," and that appropriate compliance efforts on the part of suppliers should be considered credit "that turns into dollars."

Morris also defends the OIG's current posture concerning self-disclosure in relation to whistle-blowers. He says whistle-blowers are free to come forward even when negotiations between providers and the government are under way, as long as there has been no public disclosure of the facts brought by the whistle-blower.

"At present, there is no inconsistency," he argues. But he also notes that there's a growing body of case law over what constitutes "original source material" brought by whistle-blowers.

In addition to the audit provisions, Morris says many providers entering into CIAs express concern about the OIG's exclusion authority when it determines the provider has materially breached the terms of the CIA.

In her letter, Brown defended this practice, but said the OIG will forego the exclusion remedy if the provider has made an "appropriate self-disclosure," and has demonstrated "sufficient trustworthiness." ■

NPDB data bank

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entrust their health and well-being," he asserted.

But Bliley had few backers. "When we created the [data] bank, we assured doctors that we would not open up the bank to the general public because the information requires interpretation and could result in an explosion of malpractice suits," argued Rep. Fred Upton (R-MI). "If we break this commitment, how can we expect doctors and other health care providers to trust us when we tell them that if they come forward and report errors they will not be singled out for punishment or open themselves up to malpractice suits?"

Democrats charged that the hearing was retribution for the American Medical Association's support for a Patient's Bill of Rights bill introduced in the last session.

"This subcommittee should not be used as an instrument of retaliation for political agendas," demanded Rep. Bart Stupack (D-MI).

Rep. John Dingell (D-MI), the ranking Democrat on the subcommittee, listed a host of potential minefields associated with opening up the NPDB, including "ample evidence" that entities already required to report have not done so on a consistent basis, and that there are considerable variations

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across states and hospitals regarding reporting frequency. He pointed out that the NPDB's own executive committee reported last November that 60% of all hospitals had yet to file a single adverse action report to the data bank.

Bliley's scheme is not short on detractors outside Congress, either. "I think there are a lot of problems attendant to it," asserts **Mark Kadzielski**, the partner in charge of the West Coast health care practice of Akin Gump in Los Angeles.

"This is going to give out false, misleading, inaccurate information, which is going to be difficult for the public to judge," Kadzielski argues, "particularly in light of the very salient fact that 60% of the hospitals have never filed a report since the data bank was initiated ten years ago."

"If you looked in there and don't see your doctor, it does not give you much confidence," explains Kadzielski. "On the other hand, if you look in there and find your doctor, it does not mean he is a bad guy. Either way, the concern is that misleading conclusions will be drawn from this amalgam of data, which in itself is not very comprehensive or complete," he adds. "If it is going to be used to judge competency, it needs much more sophisticated questions before you can come up with that determination."

Dick Davidson, president of the Chicago-based American Hospital Association (AHA) contends that certain types of information can and should be made public, including criminal convictions and actions taken by the state licensing boards. But he adds that malpractice information that does not distinguish between physicians sued for unnecessary care and those who settled for expediency will only sow confusion.

Davidson also says the internal hospital peer review process, which allows health care practitioners to candidly review the performance of their peers, could be undermined by Bliley's proposal.

"It's not that we don't think some of the information should be open to the public," argues AHA spokeswoman **Dionne Dougal**. "It's just that we want accurate information they can understand."

Dougal also questioned the NPDB committee's estimate that 60% of hospitals have never reported. Rather, she says, hospitals have other systems in place to take action regarding physicians before they are required to report those incidents. ■

DOJ's priorities

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I. Managed care. According to Bentivoglio, the growing trend toward Medicare managed care means more anti-fraud enforcement activity in that area. He says most current investigations in this area involve straightforward fraud, such as kickbacks and false cost reports. But he adds that a handful of investigations are also under way into a knowing failure to deliver promised health care services.

II. Nursing homes. Bentivoglio credits the October 1998 meeting between DOJ, the Department of Health and Human Services' Office of Inspector General (OIG) and state enforcement authorities with bringing federal and state oversight and survey bodies into the nursing home investigative process. Several regional meetings have "done wonders" in uncovering conduct that in some cases is "truly horrific," he says.

Note: The OIG is set to release the final nursing home compliance plan later today. Look for analysis in the next issue of *Compliance Hotline*.

III. Pharmaceuticals. The latest target of government anti-fraud efforts in health care is no doubt pharmaceuticals, according to Bentivoglio. He said this area of growing concern ranges from "pill mills" to far more sophisticated scams. Bentivoglio said specific targets include substitution scams, automatic and partial refills, and failure to disclose rebates. ■

Integrated systems deal with kickback issues

Integrated delivery systems (IDS) face a unique and growing array of legal pitfalls based on the changing nature of those organizations, says **Dan Roach**, vice president and corporate compliance officer for San Francisco-based Catholic Healthcare West (CHW).

Roach says one of the primary legal issues is the application of the anti-kickback statutes to related and affiliating organizations. He says systems must understand that the anti-kickback statutes are extraordinarily broad. In fact, read literally, those statutes would bring the nation's

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health care system to a grinding halt, he argues.

"The reality is that every time you have a physician who becomes a medical staff member, I could make an argument that every patient she admits is a violation of the kickback statute," he explains. "The good news is that no one has read it that broadly."

According to Roach, there are specific vs. practical exceptions. But he says that development of a consistent process for transaction review is no easy task. For example, Roach says CHW acquired a facility several years ago and structured the deal as an asset acquisition with CHW refusing to assume certain liabilities. "Everyone agreed that we would change the provider numbers immediately at the point of the transaction," he explains. But on the day of the transaction, it turned out that the facility's computer system could not accommodate the new provider numbers.

Use of the old provider numbers continued until they could upgrade their system, which took about six months. Roach says the government is now arguing CHW has successor liability because CHW had opted to use the old provider numbers. "Even though the transaction was structured correctly, it wasn't executed appropriately," he says. "This is a real concern.

"The key to avoiding successor liability includes an asset purchase and not to assume undisclosed liabilities." In addition to obtaining new provider numbers, systems should avoid government receivables, he cautions. "When you take accounts receivable as part of the acquisition of an organization and part of that includes receivables for Medicaid or Medicare payments, the government argues that you have assumed the liability for the billings that generated the receivables."

Other areas of concern for the IDS include:

- **Three-day window rule.** According to Roach, the biggest hurdle for IDS is the three-day window rule, which applies to owned or operated subsidiaries. "The general view is that if the facility providing the diagnostic tests is owned or operated by the admitting facility, the tests fall within the rule," he says.

But there is often a large gray area, he warns. "You have all kinds of different relationships and different levels in the organization and the rules are not at all clear about how you apply the three-day window in these contexts," says Roach.

- **Tax issues.** Roach notes that many integrated systems are nonprofit organizations with for-profit subsidiaries. That can lead to questions over what portion of a physician group's losses can be funded before someone argues that the sole motive for doing so is to induce referrals and keep those physicians in the hospitals. "I believe this is an unanswered question, and I think that the recent OIG advice on the gainsharing issue simply muddies the waters," he argues.
- **System financing issues.** System financing issues also create risk, according to Roach. Access to capital is becoming more difficult and Roach says lawyers are becoming increasingly concerned about issues that need to be disclosed to bond holders. In addition, there are limits on an organization's ability to spend tax-exempt bond proceeds on nonexempt activities.
- **Site of service designation.** Roach also points to licensure and accreditation issues as potential trouble spots. In one case, he says a system merged its lab into a "consolidated lab" and performed certain tests in one location and other tests in another. "But it turned out that we didn't have the appropriate CLIA [Clinical Laboratories Improvement Amendments] certifications." Many times, the decisions about where the tests were performed were simply based on who had the best equipment and the CLIA certification issue was overlooked. "In other cases, the lab tests were being performed in the right place but we were simply using the wrong number and it looked like we were not appropriately performing the tests."
- **Conditions of participation/staffing issues.** Roach says systems should also guard against running afoul of Medicare's conditions of participation and staffing requirements. For example, he notes one investigation involving a physician who had been a sole practitioner. The physician opted to merge with a local clinic a few miles away and began to spend three days a week at the new clinic and two days a week in the old clinic.

Unfortunately for the physician, patients kept coming to the old clinic and nurses kept doing the same things they had always done, and soon there was a knock on the door from the OIG. "The OIG said these patients are being seen, but there is no physician on site, [and] there is inadequate supervision. And by the way, it is being billed under your provider number," Roach reports. ■