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CMS administrator working to overhaul regulatory process

Centers for Medicare and Medicaid Services chief also wants to streamline number of carriers

Late last week, **Tom Scully**, the newly appointed administrator of the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) told the Senate Special Committee on Aging that he is working with Secretary of Health and Human Services (HHS) Tommy Thompson to radically overhaul the current regulatory process and slash the number of carriers that process claims.

Changes would include small concrete actions to lighten the burden on health care providers. For example, Scully said CMS will offer advance notice of regulatory changes and then publish its entire rule making one day each month. He said that will help avoid the agency's "regulatory strafing runs" and the need for hospitals to have a full-time law firm working for them.

Scully's announcement came July 26 at a hearing on Medicare fraud enforcement, at which members of the Senate Special Committee on Aging spent more time talking about overzealous prosecutors than fraudulent health care providers. Sen. **Larry Craig** (R-ID), the committee's ranking member, said health care providers are "terrified" of exposing themselves to "zealous audits" and "dramatic penalties for innocent mistakes."

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Search warrants: An audit investigation road map

Most investigations begin with subpoenas rather than search warrants. But **Robert Griffith**, a health care attorney in Boston, says that even though the vast majority of information is collected through subpoenas, attorneys should train their clients how to respond to warrants as well.

One reason to focus on search warrants is that once they are issued, there is no time to think, says Griffith. Beyond that, he says the same road map that is used for search warrants can be applied to subpoenas.

Most warrants are daytime warrants that must

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LTC giant hit with quality mandates; hospitals next?

The Department of Health and Human Services' Office of Inspector General (OIG) announced a broad corporate integrity agreement (CIA) with Sun Healthcare Group last week. The agreement marks the second time the OIG has used an integrity agreement to impose sweeping quality-of-care requirements on a major long-term care provider. Now the question is whether the OIG will begin using the same tactic with other health care providers, including hospitals.

Stuart Gerson of the law firm Epstein, Becker and Green in Washington, DC, says the chances are significant that qualitative requirements will continue to surface in CIAs. "Whether it is hospitals or other places, we will see it again," he says. "CIAs are ever-expansive," he adds. "They have gone up in years and gone up in depth, and we now have a broader coverage of issues.

According to Gerson, the OIG takes the position

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Regulatory process

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Scully told the committee that HHS is establishing a senior-level regulatory reform group to review the current regulatory framework and determine which rules should be better explained, which should be streamlined, and which should be cut altogether.

In place of the current 72 carriers, which have little incentive to operate efficiently, Scully said HHS wants 18-20 highly motivated, well-trained carriers. Most of those will likely be Blue Cross carriers, he added.

Another target on Scully's list is Medicare's enormously complex appeals process. He said the "long, tortuous process" that providers now face must be realigned. Describing the maze of entities that providers must currently deal with to appeal payment decisions, Scully told the committee, "It would be a frightening organizational chart if I shared it with you."

Asked by Sen. **John Breaux** (D-LA) whether new tools were needed to combat health care fraud, Scully responded that the current arsenal is just about right, but how that arsenal is used sometimes is another matter. He also took exception with some provisions in health care reform legislation introduced by Rep. John Murtha (R-PA) because he said it goes too far. One such provision would prevent more than one audit of any particular type of claim each year.

Scully admitted that the agency's estimate of $12 billion in health care fraud is "not all that solid." He estimated that only about one-third of that is actually fraud, with the remainder accounted for by honest billing mistakes largely due to Medicare's complexity.

Scully, who spent the last six years at the Federation of American Hospitals in Washington, DC, argued that most hospitals have cleaned up their act and that remaining fraud probably is more spread out among smaller providers, including physicians. The problem is that hospitals and other large health care providers make much better targets, he added, noting that only 25 physicians faced significant disciplinary action last year.

Following Scully, the Chicago-based American Hospital Association (AHA) took aim at the "duplicate investigations" carried out by the Department of Justice (DOJ) and the Health and Human Services Office of Inspector General (OIG), which have concurrent jurisdiction over fraudulent claims. DOJ uses the False Claims Act, and the OIG uses civil monetary penalties. While this should provide flexibility for allocating resources, argued AHA, in practice it has permitted the OIG to second-guess decisions of the DOJ.

AHA Special Counsel **Joseph deGenova** said attempts by the OIG to place a hospital under investigation for the very same issues examined and found to be without merit by DOJ should not be permitted. Assistant Inspector General **Lew Morris** countered that there is "a different standard" and "very different calculus" between the two agencies. ■

Quality requirements

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that it can enforce quality issues even if that is not the central issue in the case at hand.

That theory has never been tested, he adds. "Nobody has ever taken it on because of the exclusion power of the OIG," he explains.

Marie Infante, a health care attorney with Mintz Levin in Washington, DC, says that quality-of-care issues in CIAs would be a "startling new development" for hospitals to cope with. But it is altogether possible that certain quality issues may creep in, she says.

There already are signs that quality-of-care

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issues are showing up more often on hospital radar screens, in general. For example, when the Centers for Medicare and Medicaid published new Conditions of Participation two years ago, it included restraints and seclusion and other related issues. Hospitals also are facing more frequent surveys as well as new self-reporting and sentinel-event requirements.

Despite those factors, and despite last year's publicity regarding the number of patient deaths attributed to medical errors, Infante says that nursing homes are still in a class by themselves when it comes to vulnerability over quality-of-care issues.

What sets nursing homes apart is the survey process, explains Infante. "Nursing homes don't have the insulation of deemed status," she says. "That makes them much more accessible and open to creating the kind of public information that the survey reports represent under much stricter scrutiny."

Infante also points out that the OIG's guidance for nursing homes highlights quality of care, resident rights, abuse, and neglect as significant risk areas.

The CIA for Sun, one of the nation's largest operators of nursing homes and long-term care services, is part of the resolution of ongoing investigations of the company by the OIG and the Department of Justice and modeled after the OIG's agreement last year with Vencor, another long-term care giant.

Like Vencor, Sun has filed for protection from its creditors under Chapter 11 of the bankruptcy code. In order to be discharged from bankruptcy, the federal government must acquiesce in the plan of discharge, and the government has not been shy about using that leverage. The CIA itself will not be made public until that process is complete.

The five-year CIA requires Sun to engage a team of independent monitors selected by the OIG to provide an ongoing assessment of these systems and quality-of-care measures. In addition, the company will be required to conduct training every year for all employees and operate a confidential disclosure program for its employees, contractors, patients, and families.

Sun also must perform a semiannual screening of all employees and contractors to determine their eligibility to participate in federal health care programs and create a comprehensive internal audit and review mechanism that reviews that adequacy of its system of internal financial controls, accounting practices, financial reporting practices, and other internal audit and review functions.

It also must engage an independent review organization to perform financial and compliance reviews in conjunction with its own staff that are aimed at identifying and eliminating payment errors.

Quality-of-care only will be one of the many issues debated next week at an invitation-only roundtable discussion organized by the OIG that will include dozens of government and private-sector experts with a stake in how CIAs are being developed and implemented. ■

Search warrants

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be executed between 6:00 a.m. and 10:00 p.m. According to Griffith, the first step in dealing with a subpoena is to designate a contact person at the client's office whose job it is to contact outside counsel.

In fact, he says, every client should have a person who is trained to exercise efficient damage control and contact the attorney within the first 10 or 15 minutes. "It doesn't matter if we are talking about subpoenas or investigations," he adds.

First, he says, clients should get their cards and ascertain all agency affiliations. Then they should obtain a copy of the warrant or subpoena along with any attachments.

Warrants authorize agents to search specific information and seize specific property, notes Griffith. "Someone needs to be doing a checklist, just as you would with a subpoena," he says. "You always want to limit the scope of the warrant."

He says the client should obtain receipts or inventory for the property received and ask for copies of documents essential to conducting

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business without impeding or obstructing the agent's efforts to execute the warrant.

It is important to remember that search warrants do not authorize employee interviews, adds Griffith.

If interviews are conducted, he says, it is important to note exactly who was interviewed, the questions asked, and the answers given. A grand jury subpoena also may be served, but that does not mean that the employee must consent to the interview during the search, he explains.

If counsel is unavailable when the warrant is executed, an employee should be assigned to monitor the agents conducting the search, says Griffith. In addition, notes should be taken regarding the agent's conduct as well as the areas searched and the documents or items seized. "Employees should not volunteer information," he asserts.

Finally, Griffith says, counsel should make sure that all of the agents have left at the end of the search and compile a list of all the areas searched. For each area searched, counsel should identify the personnel with knowledge of any missing items and list all items taken by agents. ■

Home health agencies face new challenges under PPS

For many years, home health agencies (HHAs) have been under intense pressure to reduce utilization. That's because, under cost-based reimbursement, they were rewarded for serving as many patients and providing as many visits as possible.

Under the Medicare home health prospective payment system (PPS), which includes incentives designed to curtail utilization, the spotlight is now focusing on underutilization, as well as patient dumping and patient abandonment.

Since HHAs that control utilization are likely to show more profit, the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) now is worried that agencies will "dump" high-cost patients.

The Department of Health and Human Services' Office of the Inspector General (OIG) already has indicated that this may constitute fraud. Unfortunately, the CMS survey process is subject to the interpretation of individual surveyors, industry experts say.

The audience with CMS and the OIG was organized by Rep. Bill Thomas (R-CA), chairman of the powerful House Ways and Means Committee, and the Washington, DC-based National Association for Home Care.

Steve Pelowitz, director of CMS's Office of Survey and Certification, promised to investigate the incidents. He also emphasized that surveyors are obligated to perform entrance and exit interviews and that CMS's survey role is oversight and reporting, not harassment.

Elizabeth Hogue, a health care attorney in Burtonsville, MD, cites one HHA that received a condition-level deficiency based on abandonment of a patient, even though the patient was transferred to another agency and care was continuously provided consistent with the patient's plan of care.

To prove abandonment, she says, the OIG must show that providers unilaterally terminated the provider/patient relationship without reasonable notice when further attention was needed. "Abandonment requires unilateral termination of the relationship," she asserts. "Patients who terminate relationships with providers have not been abandoned."

On the other hand, if the agency intends to terminate the relationship because it lacks resources to meet patients' need consistent with the Medicare Conditions of Participation, the provider's actions could amount to "patient dumping" from the OIG's perspective, especially under a system of prospective payments, she adds.

Scott Lara, director of government affairs at the American Home Care Association in Jacksonville, FL, says he remains concerned that under PPS, surveyors and auditors sometimes are on "witch hunts."

"HHAs are being forced to reduce care while at the same time ensuring that patients have the best outcomes available," he asserts.

(See the next issue of Compliance Hotline *for tips on how to avoid deficiencies in the home health survey process.)* ■