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Terrorist attacks paralyze legislative compliance agenda

White House and Congress limit their scope of activities to 'essential tasks'

This month's terrorist attacks on New York City and the Pentagon have effectively paralyzed all "nonessential" government work in Congress and at the White House. For compliance officers, that reduces the threat of new anti-fraud measures becoming law this year but also damages the prospects of several promising reforms.

On one hand, Congress and the rest of government are anxious to show that the terrorist attacks have not hampered the government's routine, but congressional staffers say the atmosphere is anything but business as usual and predict that little will be accomplished apart from budget-related items.

A spokesperson for the House Ways and Means Health Subcommittee says the status of things on Capitol Hill remains very fluid. An abbreviated session last week will be followed by another abbreviated session this week. The only health care-related item tentatively scheduled is a hearing on Medicare contractor reform later today that was postponed immediately after the attacks.

A Senate Finance spokesperson echoes those sentiments, predicting that Congress will have little time or energy for anything apart from completing the budget and crafting an economic stimulus package.

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Consultants offer providers a double-edge sword

The Health and Human Services' Office of Inspector General (OIG) maintains that hospitals can successfully outsource a variety of compliance tasks, including training and education, maintaining hotlines, auditing, and sometimes even the compliance officer function itself.

But recent congressional investigations that uncovered consultants bilking federal health care programs highlight only one of the many problems that can arise if health care consultants are not screened and selected carefully and the agreements made with them are not carefully and thoughtfully crafted.

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Research compliance threats loom large

With teaching hospitals and other research organizations coming under increasing scrutiny by federal investigators, specially tailored compliance programs for research activity have become a necessity, says **Lisa Murtha**, chief audit & compliance officer at Children's Hospital of Philadelphia.

Clinical research is tied directly to federal funding through the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), and corporate sponsors of clinical trials have a vested interest in making sure research studies are conducted in compliance with a myriad of regulations.

In addition, Murtha points to a growing public demand for improved internal controls as a result of several recent high-profile cases.

According to Murtha, organizations engaged in research face numerous pitfalls, beginning with

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Legislative agenda

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The prospects for a patients' bill of rights or prescription drug benefit have been all but obliterated and along with them any prospect that other items might be attached to those measures, says **Mary Grealy**, president of the Health Care Leadership Council in Washington, DC.

Ironically, congressional action has been frozen at a point when there are just as many promising legislative opportunities for health care providers as there are threatening ones. One such bill, commonly referred to as "the provider relief bill," would have set stringent parameters for the Health and Human Services' Office of Inspector General and the Centers for Medicare and Medicaid Services (CMS) to abide by when sampling provider claims.

Grealy predicts that any relief providers do see will be administrative in nature. CMS Administrator **Tom Scully** recently told the Senate Special Committee on Aging that he is working with Secretary of Health and Human Services Tommy Thompson to radically overhaul the current regulatory process and slash the number of carriers that process claims. While the long-term agenda remains intact, progress on specific items that may have offered hospitals some relief, such as changes in the appeals process, has been delayed. ■

Research compliance

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conflicts of interest for investigators who have ownership interests in companies that are co-owned by sponsors. "These are risks that you deal with every single day," she warns, adding that investigations into these conflicts are certain to continue.

Any institution that does not have a conflict of interest committee comprised of investigators and other key representatives should consider establishing one, Murtha says. She adds that when investigators are given the opportunity to discuss these issues with their peers, they typically arrive at the appropriate conclusion. "Peer pressure can be a valuable thing, so I would exploit it as much as possible," she explains.

A second area receiving significant attention is billing for clinical drug trials and the way sponsors are charged for costs related to research. However, Murtha warns that most academic medical centers do not have adequate internal controls in place to determine which types of tests might be appropriately reimbursable through Medicare, Medicaid or a private insurer.

According to Murtha, these problematic scenarios can arise under a variety of situations. For example, a patient who enters the hospital as an inpatient may be identified as a potential research subject and some of the initial tests performed can be charged to the grant. However, organizations need guidelines to handle these situations, and research institutions that lack appropriate guidelines may be double billing, she adds.

John Steiner, director of corporate compliance at the Cleveland Clinic Foundation (CCF), reports that when he assumed that position three years ago he found a general lack of awareness regarding the complex requirements surrounding clinical research among both investigators and support staff.

Initially, Steiner says he met with various parties, including legal, internal review board, support staff, nurse researchers, research accounting, and senior management. "I was able to figure out very quickly that the lack of consistency was real," he reports.

To remedy that situation, Steiner sought to "build bridges" among various groups, such as

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those with a knowledge base of Medicare payment and coverage issues and those who support the primary investigators. That way, the people who understand reimbursement and patient flows are in a position to flag potential problems.

Likewise, staff who directly support investigators must know how and when to look for changes in national coverage or local medical review polices that affect payment and coverage for clinical trials, he says.

In addition, Steiner says someone must be responsible for scrutinizing contracts and determining whether commercial payers are adequately looking at clinical research issues such as coverage, as well as whether the principles under managed care and commercial pay contracts are the same as they are for Medicare. That way, research organizations can start to drive all their billing and coverage systems in the same direction, he explains.

In terms of developing a research compliance plan, Steiner says one good place to begin is with *Proactive Compliance Site Visits 2000*, a 12-page document released April 4, 2001, by NIH that contains findings and observations from visits to 20 organizations nationwide.

Steiner says that document can be used to zero in on examples of compliance, which then can be tied back to very specific steps that NIH either witnessed or indicated that it would like to see. Using that report, Steiner says he drafted an internal document that outlines a variety of areas such as roles and responsibilities, adequacy of delegation, and follow-up steps, which was used for internal gap analysis to plan further compliance measures.

Murtha agrees that research organizations should focus their attention on the risk areas that require the establishment of a compliance program, such as undefined roles and responsibilities. "Because investigators tend to work in silos, they are the masters of their domains," she warns. "They basically do what they want to do."

Decentralized administration is another issue that poses risk, according to Murtha. She says that one of the projects that Children's Hospital currently is undertaking is to centralize the core functions that all of its investigators engage in that are duplicated around the institution.

Murtha adds that while she anticipated resistance from investigators, the repeated emphasis that already had been placed on compliance actually led them to embrace this process as a way to alleviate those pressures. ■

Using consultants

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"I am glad they are working to extricate the bad apples we have in our industry," says **Roy Snell**, CEO and executive director of the Philadelphia-based Health Care Compliance Association (HCCA). "But we need to understand that there are many highly qualified and ethical consultants as well," he adds.

Snell says the first thing hospitals should do is know who they are dealing with. One way to do that is to look for certification. In fact, one of the purposes of establishing HCCA's certification program was to help potential employers of consultants and nonconsultants more easily identify individuals with a baseline knowledge of health care compliance, he adds.

HCCA certification requires significant education and experience and represents a relatively inexpensive testing process, Snell says. But even when hospitals select an appropriate consultant, many things still can go awry.

Here are some potential pitfalls and possible protections that health care attorney **Gerald Griffith** of Honigman Miller in Detroit says providers should look for when establishing a consulting relationship:

- **Don't shop your secrets.** Griffith says providers must make sure that consultants don't have license to take the experience and ideas gained from the engagement and teach a competitor how to do the same thing based on what they just learned.

"Ideas and experience are a consultant's stock and trade," asserts Griffith. He says hospitals should explore provisions to guard against this, as well as the possibility that consultants may wind up hiring certain employees at the end of the engagement.

- **Limit your liability.** The first opportunity to

limit exposure is likely to come up in the course of the engagement letter, Griffith says. That means providers must gauge their liability exposure, which is likely to vary depending on the type of engagement.

During the bid process, he says, providers should spell out specific tasks and deliverables as well as specific duties and the standard of care for performing those duties.

Griffith says providers should review sample contract terms in the request for proposal letter. "Then you can find out relatively early in the process what key contract terms you feel strongly about and may pose a problem with the consultant," he explains. "That may affect your decision in the selection process."

♦ **Avoid conflicts of interest.** Griffith says providers must avoid the appearance of conflict in case they need to use the consultant's report for some purpose in the future.

The independence of the consultant may be necessary for a variety of reasons, such as justifying the fair market value of a transaction. If consultants have a stake in the outcome, such as being paid based on the percentage of the purchase price of a hospital, it may undermine that credibility, he warns.

♦ **Pay attention to customer satisfaction and standards of care.** Griffith warns that providers will face resistance if management and the employees who have to deal with the consultant are not satisfied and don't understand why the consultant is there and what needs to be achieved. "That goes hand-in-hand with a particular standard of care and how you want the consultant to perform," he explains.

♦ **Control the engagement.** Griffith says providers must make sure that consultants are appropriately monitored so that duties are performed and time lines are met. In order to foster the appropriate environment, providers must have the participation and buy-in of management as well as the involvement of in-house counsel, he says.

♦ **Avoid consultant-speak.** Finally, Griffith says that providers must avoid using catch phrases in contracts and make consultants spell out what it means to be "word class" and "a market leader." ■

OIG report highlights use of on-site visits

The Health and Human Services Office of Inspector General (OIG) last week released the findings of its July 30 roundtable aimed at coming up with solutions for the most onerous aspects that corporate integrity agreements (CIAs) are placing on hospitals and other health care providers. One of the areas that now looms large is site visits. "The thing that is terrifying for most people is employee interviews," says **Jamie Whitten**, a health care attorney with Jones Day in Washington, DC. "It can be an overwhelming experience."

According to an OIG program analyst, there were 18 sites visits in FY 2000 and approximately 30 site visits in FY 2001. In addition, he says, the Centers for Medicare and Medicaid Services (CMS) now has 25 program safeguard contractors engaged in this process. The OIG also has signed an agreement with Tricenturion in Columbia, SC, to conduct billing reviews and verification audits to support OIG compliance monitoring efforts in the next contract year, Whitten reports.

During on-site visits, the OIG now meets with compliance staff, the board of directors, and employees to review compliance systems and test audit procedures and claims review. But Whitten maintains that it is a misconception that agents participate in site visits. Typically, the on-site review team is made up of compliance unit staff members and sometimes a CMS representative.

He notes that recent OIG Q&A on-site visits indicate that health care providers can have somebody present during the interview, but the OIG requests that it not be the compliance officer because questions asked during the interview might specifically relate to the compliance officer's performance.

Regardless of how that is handled, Whitten says, hospitals must approach these interviews very carefully. "They should know in advance who is going to interview and prep them," he warns. "They should be handled just like any other government investigation."

The OIG report is available at www.hhs.gov. ■