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Health Care Program Compliance Guide

MONTHLY FOCUS

In Bad Economy Hospitals Cannot Afford Ineffective Compliance Efforts, Attorney Says

In today's challenging economy, hospitals looking to cut their budgets may believe that compliance department needs can be put even lower on the priority list. After all, even in good times compliance officers sometimes have a hard time getting people to recognize their relevance to hospital operations, Patrick S. Coffey of Locke Lord Bissell & Lidell LLP in Chicago told BNA.

But this is a mistake, Coffey said, since it fails to recognize that difficult economic times can create disillusioned and stressed employees and increase whistleblower and related enforcement risks. Although the hospital sector's 2008 operating results were good, he said, hospitals are seeing increasing numbers of indigent patients coming through their doors and are being forced to shelve expansion plans for lack of credit and other reasons.

Coffey's observation that the current economic turmoil increases False Claims Act risks and requires not less, but greater, focus on Medicare compliance efforts is supported by a survey of compliance and ethics professionals done in December 2008 by the Health Care Compliance Association and Society of Corporate Compliance and Ethics (see story, p. 40). According to the HCCA, the survey revealed ''a disturbing divergence of trends in compliance and ethics. While 85 percent of compliance and ethics officers surveyed believed that the current economic crisis increases the risk of a compliance or ethics failure, few thought budgets would rise to meet the challenge. And many expected a budget cut.''

''This is a very difficult period and one that will end any notion that health care is recession-proof,'' Coffey said. It is just the kind of climate in which disillusioned employees (potential whistleblowers), disturbed by reductions in force and other cost-cutting efforts, increase the risk of False Claims Act suits. Add the fact that hospitals are educating employees on the FCA and their rights to be protected as whistleblowers, and the ongoing escalation of government enforcement in the health care arena, and the necessity of even better compliance and oversight functions becomes clear, he said.

Won't-Happen-Here Syndrome

Coffey told BNA he believes hospitals already commit substantial resources and efforts to compliance and do want to do the right things. However, even though they are aware that large FCA settlements have hit others in the health care industry—on Aug. 13, 2008, for example, managed care company Amerigroup Illinois settled a $334 million FCA judgment for enrollment fraud for $225 million and a corporate integrity agreement—providers too often believe that FCA cases are ''something that happens to someone else,'' he said.

''They believe it won't happen to them because they think they're better, they're smarter.'' They also believe, often erroneously, that their existing compliance program is effective and will protect them, not realizing that many compliance programs suffer from a broad range of failings (see box, p. 39). The view that ''I won't be the one who gets hit by the bus'' ignores serious hospital cases, such as the recent settlements involving Condell Health Network and St. Barnabas Health Care System that led to ''huge penalties driven by obvious compliance weaknesses.'' Nevertheless, Coffey said he expects the general attitude to persist so long as resources for investment in effective compliance efforts are under pressure.

Enforcer's Key Question

When alleged fraud or abuse comes to the government's attention, the first question the hospital administration is asked is, ''Why didn't your compliance program identify and head off this problem?'' It may be the first question the board of directors asks too. Some of the reasons for ineffective programs, even ones that appear well-designed on paper, are that compliance is widely seen as a ''matter for the lawyers'' and is not a business priority, Coffey said.

The result is that the supportive ''tone at the top'' is usually absent or insufficient, compliance over-

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sight is lacking, and organizations fail to offer ongoing messages about the importance of compliance and their commitment to doing the right thing. Making compliance a performance review matter and giving employee rewards and recognition for good compliance records would help show the compliance commitment is sincere, he said.

''It is safer to have no compliance program than to ignore the one you have held out as in force,'' he said.

Detecting or, better yet, preventing wrongdoing is what matters and pays dividends with enforcers, he said, while failing to operate in conformance with adopted compliance programs adds governance issues to the allegations and risks aggravated sanctions. If an entity consistently fails to address evolving compliance risks, the government likely will dictate compliance regimens and impose more onerous settlement terms.

Without ongoing assessments, an organization cannot know its program is working and has earned employee commitment. But thorough assessments require resources, and requesting these means competing with other business priorities, a difficult fight even in good economic times. Providers just have to recognize that preventing and detecting wrongdoing before enforcers do will pay big dividends up front and, even if enforcers do become involved, will lead to better settlements, Coffey said.

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PATRICK S. COFFEY, LOCKE LORD BISSELL & LIDELL LLP, CHICAGO

Assessing Compliance

One way to assess a program is to analyze the use of corporate hotlines and other available mechanisms for employees to report concerns, both barometers of how well a compliance program is functioning. Enforcement authorities evaluate hotline usage and other efforts to spur reporting in the event of a problem or whistleblower claim. They will investigate to uncover any routine failure to advertise or advocate the use of hotlines or other means to report concerns.

Hotlines must be widely advertised and can be operated either internally or by a third party. If someone in the health care organization answers the calls, it should be a compliance officer or other person who has been trained to handle complaints confidentially. The advantage here is that compliance personnel are able to advise callers in line with the organization's policies. An obvious disadvantage is that employees may feel less comfortable reporting to someone they know. Whether internal or external, however, hotlines are not productive unless employees feel secure and justified in using them.

Interactive case studies and other modes of education can improve understanding and increase internal reporting. But too often compliance education is dull, ineffective, and fails adequately ''to communicate compliance basics, never mind explain the FCA or other risks guiding the compliance effort,'' Coffey said. The provider must send frequent, tailored, and meaningful messages dealing with FCA and whistleblower issues. Enforcement authorities and other external speakers can help convey the commitment to compliance and the reasons it matters, he added.

Employee buy-in is critical, he said. Failing to get employees on board may well be the biggest problem hospitals face in establishing an effective compliance program. Many enforcement authorities describe programs without such buy-in as being ''disconnected from corporate reality.'' Employees do not view the compliance commitment as sincere and do not believe their managers are genuinely receptive to reports of concerns. At the same time, managers erroneously believe that employees see them as approachable and would not fail to report or disclose problems.

Coffey located the problem in middle management. ''It is counterintuitive that a provider would not want to address a problem itself but instead risk government involvement,'' he said. Chief financial officers, chief executive officers, and general counsel are clear on that, but they often are not the source of the problem. ''It's the manager who tells his or her employees that there is an open door for reporting any problems when what employees hear isn't 'I'm here to help,' but a very different message. They sense a lack of commitment to addressing their concerns.'' Some of this is poor training, but some is the manager's lack of sensitivity, he said. ''Managers don't appreciate that it is not easy to raise concerns or problems internally, and as a result people don't.'' Few companies convince employees that they want them to report matters and will protect them, yet without employee assistance, no organization can protect its interests by identifying and fixing compliance-related problems, Coffey said.

Without employees backstopping the compliance officer, it is even more important for providers to have a robust compliance effort, Coffey said. Providers should follow enforcement trends, regulatory guidance, and FCA case settlements to define and focus on key compliance aspects. Studying these will reveal that most whistleblower and enforcement cases ''don't involve issues noted in the [Department of Health and Human Services Office of Inspector General's] annual work plan,'' Coffey said. Studying settlements is valuable because they set the bar for related-industry participants and reinforce or establish the government's definition of ''effective'' compliance. Programs should not remain static when much can be learned from government-dictated compliance measures, Coffey said, adding that the most useful study of settlement terms includes ''comparing them to your own organizational approach.''

Handling Whistleblowers

The dismissal of anonymous reports needs to end, Coffey said. ''I can't recall ever handling a qui tam case where there wasn't an effort on the employee's part to first work within the system,'' he said. Whistleblower and enforcement actions arise when employee-reported complaints are ignored or mishandled, he said.

In fact, advance planning for handling reported compliance problems is still a developing best practice, Coffey said. Providers seem unprepared and ill-equipped to assess these reports and respond in a way that would manage FCA exposure and deter people from seeking redress outside the organization, he said. Managers should have much better understanding of the true dynamics associated with employee reporting. They need to appreciate ''how incredibly hard it is for them to make these reports,'' he said.

Once a report is made, organizations need to be able to assess the potential liabilities, formulate adequate corrective action, and understand the enforcement response. Improper internal investigation serves to aggra-

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Reasons Compliance Programs May Not Reduce Risk or Exposure to FCA Liability

The following reasons compliance programs do not work as intended are adapted from a Feb. 11 presentation at the American Health Lawyers Association Hospitals and Health Systems Law Institute by Patrick S. Coffey; Associate University Counsel Chris J. Mollet, University of Illinois at Chicago; and Linda A. Wawzenski, assistant U.S. attorney for the Northern District of Illinois:

- compliance is not a business priority,
- programs do not operate as written,
- programs do not focus on heading off claims,
- employee training is dull and ineffective,
- there is a lack of ongoing and meaningful risk assessment,
- hotlines are not sufficiently promoted,
- employees do not trust the compliance commitment so do not report concerns,
- managers do not understand why employees are reluctant to report perceived problems,
- significant enforcement settlements with other companies are ignored or quickly forgotten,
- organizations are not prepared to handle internal investigations and routinely mishandle internal reports,
- disgruntled employees are discouraged and dismissed,
- whistleblowers are not protected, and
- difficult economic times are allowed to undercut compliance efforts.

vate problems. While the compliance officer and inside counsel are essential, they also may need protective distance, he said.

Too many managers believe that compliance reports are the product of ''disgruntled employees,'' a term that suggests both an unwarranted attempt to demean such employees and a disregard for compliance, he said. Organizations need to focus on the substance of the reported conduct and address its merits. It should be left to U.S. attorneys and other enforcement authorities to evaluate a whistleblower's motivation and credibility, he said.

Employers should protect all those who bring information forward. Compliance training should teach that prohibiting retaliation is part of compliance. Protection is particularly important when whistleblowers have been internally identified or suspected yet remain in their positions. A hospital that dismisses a whistleblower runs substantial risks and must do it in a way that does not increase its exposure to liability.

Reductions in force and other cost-reduction efforts run a serious risk of further aggravating disillusioned employees. Compliance resources are under pressure at a time when the law requires employees to be educated on whistleblower rights and the FCA. RIFs and a failure to make compliance a priority will generate more opportunity for false claim and retaliation actions, Coffey said.

There are many signs that government enforcement activities will only increase, Coffey said. For example, Gregory G. Katsas, assistant attorney general for the Justice Department's Civil Division, commented in a DOJ press release Nov. 10, 2008, ''Now, more than ever, it is crucial that taxpayer dollars aren't lost to fraud.'' Katsas reported that DOJ secured $1.34 billion in fraud settlements and judgments in fiscal year 2008, almost 78 percent of which were associated with whistleblower suits.

In such an atmosphere, hospitals should take all possible steps toward risk mitigation, Coffey advised.