

Compliance TODAY June 2016

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

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When it comes to regulatory compliance, prevention is key

- » Investigation and enforcement of healthcare legal violations are on the rise.
- » To ensure compliance, providers must understand regulations relevant to their healthcare organizations.
- » Healthcare organizations should look to advisors and compliance personnel for assistance.
- » How a provider handles an investigation may ultimately determine the outcome.
- » The time and expense necessary to ensure ongoing compliance is better spent upfront than defending a regulatory violation.

Christina M. Kuta (ckuta@ralaw.com) is an Associate in the Chicago office of Roetzel & Andress, LPA, V @ChiHealthLaw

> sk any attorney concentrating his/her practice in the health law field for a list of current trends in this area of law, and undoubtedly the issue of regulatory compliance will be of primary importance. In 2014 alone, the federal govern-



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ment recovered nearly \$2.3 billion related to false claims made under the Medicare and Medicaid program, with a total recovery of \$14.5 billion since January 2009.1 With so much alleged fraud, waste, and abuse in healthcare payments, the government continues to aggressively investigate and enforce potential regulatory vio-

lations in all facets of the healthcare delivery system. From the solo practitioner physician to the large academic medical center, no one industry or single player is immune. So what are some common actions that all providers, regardless of service type and size, can take —both to ensure regulatory compliance and address concerns?

Understand the rules

Commonly, providers fail to understand the specific rules and regulations that apply to their healthcare organization. The proliferation of healthcare-specific laws over the past few decades (think the Anti-Kickback Statue and the physician self-referral Stark Law, for example), coupled with the added requirements related to Medicare and Medicaid billing, have created a vast rubric of healthcare policy and practice. Healthcare organizations should make it a priority to consult with administrators and compliance personnel who are familiar with both healthcare delivery and associated legal requirements. Obtaining compliance guidance from knowledgeable sources not only will work to ensure the healthcare organization is operating lawfully, but also will allow providers to retain primary focus on the delivery of actual healthcare services.

Do not rush compliance and keep current

Healthcare regulations are ever-evolving and changing. It simply is not enough for a provider to be educated on a particular

law or policy at a given moment in time. Providers must keep well-informed of new and relevant laws that impact their healthcare organization. This again underscores the need to remain educated on regulatory issues and emerging trends in the industry and to consult with knowledgeable professionals in your healthcare organization.

Do not assume your "neighbor" is operating compliantly

A common theme among healthcare providers is, "They are doing it, so why can't I?" Just because the competitor down the street does it, does not make it legal. A fundamental flaw in healthcare enforcement is that not everyone who violates the law gets caught. The mere fact that a provider is engaging in a certain activity or conduct without obvious repercussions may mean simply that the provider has yet to be discovered by regulatory authorities. A mentality of, "If we all do X, then it is not a problem" will not serve today's healthcare organizations and will not form a valid defense to a regulatory violation. Providers always should obtain independent verification of whether a component of their healthcare organization complies with existing law.

Respond to compliance issues quickly and assertively

Whether discovered by a provider through happenstance, by internal investigation, or as a result of a government investigation, when a compliance issue becomes apparent, there are certain steps a healthcare organization should take. First, it should conduct a thorough audit and investigation of the potential violation. Next, it should review the results of such analysis with knowledgeable advisors and compliance

personnel who can assess whether a violation has occurred and determine how best to respond to a government inquiry. In some instances, self-disclosing a violation may be a viable option. Depending upon the type of violation, there even may be more than one avenue for self-disclosure. Nobody likes to admit they made a mistake, but mistakes do happen. Appropriate self-disclosure may minimize fines and penalties associated with a particular violation.

Summary

Much like the practice of medicine, maintaining on-going and meaningful regulatory compliance is an art—not a science. There is no single approach that will fit the needs of any one healthcare organization. The size of the organization and scope and breadth of the services provided are just some of the components to consider when planning and initiating a long-term compliance program that meets a particular healthcare organization's needs. Universally, all healthcare organizations should look to these key concepts:

- Understand the rules that apply to you.
- ▶ Make compliance an on-going effort.
- Do not ignore "red flags."
- Get assistance from advisors and compliance personnel.
- Do not panic! Mistakes happen and can be fixed.

With these ideas in mind, spending the initial time and effort to create a tailored compliance plan will go a long way toward minimizing a healthcare organization's risk and ultimately preventing unwanted regulatory scrutiny.

[.] Department of Justice, Office of Public Affairs press release: "Justice Department Recovers Nearly \$6 Billion from False Claims Act Cases in Fiscal Year 2014" November 20, 2014. Available at http://1.usa.gov/1qMezsA