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Meet Donna Abbondandolo

Director of Compliance,
Internal Audit & Compliance,
Catholic Health Services
of Long Island *See page 16*

21

What constitutes
“reckless disregard”
under the
FCA?

Michael P. Matthews
and A. Joel Richlin

27

Compliance
as an
opportunity
for
growth

Robert E. Powers

31

Avoiding the
mourning after:
Minimizing FCPA
risk of pass through
or successor liability

Paul Pelletier and Noam Fischman

37

Ingredients
for
establishing
compliance
best practices

Andrew Finkelstein

by Andrew Finkelstein

Ingredients for establishing compliance best practices

- » Organizational inventory is required before best practices can be achieved.
- » OIG guidance creates the framework for compliance program planning.
- » Business mapping is required for inventory to efficiently fit into a framework.
- » Best practices are not off-the-shelf, but organization-specific, based upon unique elements.
- » Best practices require a constant evolution with the changing regulatory environment.

Andrew Finkelstein (abf826@gmail.com) is a Chief Compliance Officer at Tufts Medical Center in Boston.

The rare and elusive concept of “best practices”—in our industry, we hear it at conferences, we see it in print, we strive for, or maybe even claim it within our own organizational confines—but do we really know what it is? Does it even exist? Are



Finkelstein

there truly practices for a given set of procedures or particular functions that are the *best* way to accomplish those actions or achieve that result?

The perceived elusiveness of best practices comes from the desire for an off-the-shelf set, a canned collection of tools and instruments that, when utilized, place our organizations at the top of the class. Organizations vary though, and they vary so much that it would be foolish to assume that any such set of practices that might work for one organization would work with the same success in any other organization. Services, resources, finances, operations, technology—all of these components to organizations serve as unique ingredients in the larger recipe that represents what the organization is and does.

As a result, those elusive “best practices” must not be seen as clear and concise

instructions on how an organization ought to operate, rather as the potential with which it can operate. Of course, we must make some assumptions, and for purposes of this article, we’ll assume that best practices represent those methods or techniques we employ and evolve over time in an effort to achieve whatever our desired results may be (e.g., more efficient customer service, speedier manufacturing, increased profits).

Critical components

To achieve measureable and superior performance, a few critical components are required. First, inventory must be taken of the tools and resources an organization has at its disposal. Achieving best practices is only possible using the resources an organization possesses. Second, a framework is required. Even the best tools and resources are useless without a meaningful method of organizing them. Lastly, and perhaps most significantly, the utilization of those tools and resources within that framework must be not just efficient and thorough, but also up-to-date and in accordance with current regulatory and investigatory developments.

Inventory

It is logical enough that unless an organization has unlimited resources, it must utilize

those it has in its efforts to achieve its mission or goals. Information technology and human resources—the most significant inventory an organization can have—are the drivers of whatever processes an organization has in place. When one person emails another, we have a simple process which contributes to a larger practice, all in the name of achieving some larger end or goal. By documenting all of an organization's relationships like this, via its resources, a business process mapping occurs that allows an organization to assess exactly how it operates, who is responsible for the operation, and whether it efficiently meets the requirements it is intended to satisfy. Indeed, this is the underlying fabric of international quality standards such as the ISO 9000 standard for quality systems, and like ISO, the purpose of process mapping is clear:

to improve a process or make it the best, you must first understand it. Only with an assessment of our organizational inventory can we begin to understand what our capabilities are and, consequently, how we can position ourselves to best achieve our desired results.

Incidentally, if an organization is successfully able to comprehensively map its resources, an ancillary benefit is the identification of potential areas of non-compliance and/or waste. For example, if a customer service representative is responsible for handling a certain call type, and the organization repeatedly receives complaints related to the handling of that same call type, through its mapping efforts, the organization may be alerted to where that gap lies. In the same regard, mapping often yields a visual view of processes

which are demonstrative of extraneous usage of resources that are perhaps better spent in areas that are lacking similar needed resources.

Frameworks

Although inventory is critical for an organization to begin the process of understanding how it can make itself better, it is equally important to understand how to organize all of the information as it's being mapped. Fortunately for the health care industry, starting frameworks for this task and for achieving measureable results are out there for the taking, and, notably, under very good advice. The Officer of Inspector General (OIG) of the Department of Health and Human Services (DHHS) provides several frameworks that align traditional compliance elements with ongoing DHHS developments.

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Compliance program guidances (CPGs), as issued by the OIG, are voluntary guidance documents directed at various segments of the health care industry. These serve as one tool in the arsenal of instruments available to the health care com-

pliance department. Beginning in 1998 with its guidance for hospitals, the OIG has since provided CPGs for multiple other health care settings, such as home health agencies, laboratories, third-party medical billing agencies, durable medical goods suppliers, physician practices, pharmaceutical companies, and medical device companies, among others. The CPGs are all representative of the elements of what the OIG considers "in its experience" to be the effective components of a compliance program. And although voluntary, as the

largest inspector general's office in the federal government and the leading agency force behind fighting fraud, waste, and abuse (not to mention, investigations thereof) in health care, the OIG's experiences are worth a listen.

The elements are all echoed from one CPG to the next, and all consist of the following seven fundamental elements:

- ▶ The development and implementation of written policies and procedures;
- ▶ The designation of a chief compliance officer and relevant responsible bodies;
- ▶ The development and implementation of regular, effective training and education;
- ▶ The maintenance of effective lines of communication;
- ▶ The use of monitoring and auditing to aid in reduction of problem areas;
- ▶ The development of a system to enforce standards through disciplinary guidelines; and
- ▶ The prompt response and remediation of detected problems and the associated development and undertaking of corrective action.

The elements are all based upon the Federal Sentencing Guidelines,¹ detailed policies and procedures that outline sanctions for offenders convicted of federal crimes. Just as there are similarities among the various health care CPGs, there are also critical differences, albeit differences that do more to contribute to compliance best practices, rather than take away from them. The differences, notably, are in the unique risks associated with

each health care industry. For example, in the CPGs provided for hospitals,² the OIG presents fraud and abuse risk areas of relevance to the hospital industry, such as accurate claims submission, admissions and discharges, and referral statutes. Interestingly, recent amend-

ments to the Federal Sentencing Guidelines now also include periodic risk assessments as part of an effective compliance and ethics program, the so-called "eighth element."

Practicing the process

With an organizational inventory and a framework that allows for the incor-

poration of key risks, the path to best practices is only in need of effectively using the two together. To illustrate, a baker might have all the best ingredients laid out on the table, and may even have a time-tested perfect recipe, but until it's all mixed together, baked, and given a taste, his/her efforts might all be for naught. The key here is in ironic plain sight. Although the "practices" we're referring to are clearly the actual processes and procedures we undergo to achieve our desired results, the irony is that they do, in fact, require practice, trial and error, evolution, so to speak. And this is a critical step to achieving them. As work functions operate day to day, inefficiencies are exploited, creating opportunities for resources to shift, processes to change, and new methods to be tested. And it is only with those resources and within that framework that this entire process can occur.

Of course, we can look to the OIG again for some guidance in this area, and this time, it's guidance that truly defines the value of a Compliance department. As a review of CPGs

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yields consistent promotion of successful and effective compliance program elements, an analysis of industry investigations and resultant corporate integrity agreements (CIAs) and deferred prosecution agreements (DPAs) demonstrates not just the obligations an entity agrees to as part of a larger settlement, but also a glimpse into the obligations we might not have internally at our own organization.

To illustrate, a review of a pharmaceutical manufacturer's CIA related to off-label marketing and the accompanying press releases provide factual indications of what led to the investigation. Perhaps the manufacturer's agents were inappropriately marketing indications or dosages of a new drug or product because of a faulty policy, or based on incorrect training materials. Correspondingly, the CIA obligated the company to ensure greater oversight of their off-label compliance activities (i.e.; development of policies and procedures, training and education, hotline response, etc.).

This type of analysis may serve as a means for other pharmaceutical manufacturers to review their own compliance program elements and ensure they have appropriately covered FDA approved indications in their compliance policies and training. If they do not have such content, the analysis has helped to discover a gap which can be remedied. This analysis is crucial to the development of best

practices for several reasons. For starters, as stated, ongoing analyses of CIAs provides a glimpse into those areas of enforcement that the OIG sees as risky for an industry, or segment of industry, which may not have made its way into the original CPG. Over the past few years, for example, there has been an increase in the number of Foreign Corrupt Practices Act (FCPA) investigations among medical device and pharmaceutical manufacturers, despite the lack of FCPA as a risk in the original OIG CPG.

When we see our counterparts struggle with a regulatory area, it prompts us to review how well we're internally handling the same area, if at all. This may require a new inventory system, a new mapping, maybe even modifications to a long-standing training protocol. And it may not happen the first time around, but rather require repeated efforts, or "practice," to highlight the irony. If we can successfully implement these activities and we're confident that the inventory that has been framed into place accommodates the potential for error or risk, then our result has been achieved. And isn't this the point after all—to achieve the results our organizations need and desire in the best and most compliant way? ☺

1. United States Sentencing Commission: *Federal Sentencing Guidelines Manual*, 8A1.2, Application Note 3(k).
2. Original hospital CPG, 63 FR 8987, issued February 23, 1998. Supplemental guidance, 70 FR 4858, issued January 31, 2005.

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