

Don't Set It & Forget It: The Importance of Evaluating & Evolving Healthcare Compliance Programs

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On June 1, 2020, the Department of Justice (DOJ) released an updated version of its “Evaluation of Corporate Compliance Programs” guidelines for prosecutors to apply in assessing compliance program effectiveness in the context of resolving criminal investigations of companies (the DOJ Guidance). The latest revisions to the DOJ Guidance — originally published by the DOJ’s Criminal Division in February 2017 and updated in April 2019 — are not voluminous.

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Nonetheless, the changes reflect a continued and concerted emphasis by DOJ on the robustness of a company’s processes for reevaluation and, as necessary, evolution of the organization’s compliance program to ensure it is not only in place, but working effectively. Parallels to the prominence of measuring and testing compliance programs found in the DOJ Guidance for criminal prosecutions can be found in the practice and policies of the Office of Counsel to the Inspector General for the U.S. Department of Health & Human Services (HHS-OIG), which investigates civil, criminal, and administrative violations of the healthcare laws, often in conjunction with the DOJ.

According to fiscal year (FY) 2019 data released in June 2020, the federal government won or negotiated over \$2.6 billion in healthcare fraud judgments and settlements that year. The DOJ also opened 1,060 new criminal healthcare fraud investigations and 1,112 new civil healthcare fraud investigations in FY 2019. These trends have continued apace, as illustrated by the DOJ, HHS-OIG, and multiple other federal agencies coordination of a national healthcare

fraud and opioid takedown on September 30, 2020 resulting in charges against 345 defendants responsible for more than \$6 billion in alleged fraud losses, including more than \$4.5 billion connected to schemes involving telemedicine. The federal government’s investment of resources toward combatting fraud, waste and abuse in healthcare can be expected to continue in full force, irrespective of a change in political administration. Accordingly, it is important for healthcare companies to focus on maintaining flexible and effective compliance programs to not only avoid government scrutiny but also satisfy government expectations and mitigate costs in the event of an investigation.

Recent DOJ and HHS-OIG Compliance Guidance

The updated DOJ Guidance, among other things, focuses on the following as indicia of a compliance program’s strength:

- Whether the company tracks and incorporates into its periodic risk assessment “lessons learned” from the company’s own prior compliance issues or those of similarly situated companies;

- Whether the company's risk assessment is "based upon continuous access to operational data and information across functions," rather than limited to a "'snapshot' in time";

- Whether compliance personnel have "sufficient direct or indirect access to relevant sources of data to allow for timely and effective ii) periodically test the effectiveness of the hotline; and

- Whether the company routinely updates existing policies and procedures, and tracks electronic access to such documents to understand which policies are attracting more employee attention.

The DOJ's heightened focus on ensuring that compliance programs are practical, dynamic, and continuously evolving based on the organization's size, industry, geographic footprint, regulatory landscape, and other factors, is not unique among federal government enforcement and oversight agencies, particularly those charged with enforcing laws and regulations designed to ensure integrity in the healthcare industry. Specifically, HHS-OIG has for years touted the importance of periodically measuring the various elements of an organization's compliance program and modifying the program as necessary to meet changing needs. For example, it is standard practice for HHS-OIG to require all organizations entering into a Corporate Integrity Agreement (CIA) as part of a civil False Claims Act (FCA) resolution to develop and implement a centralized risk assessment and internal review process to identify and address risks associated with activities that impact federal

healthcare programs. As part of this process, companies are required by the terms of their CIAs to have their compliance, legal, and relevant department leaders annually: 1) identify and prioritize key risk areas; and 2) develop, implement, and track internal audit work plans and, as necessary, corrective action plans to address those risks.

Moreover, since 2014, HHS-OIG has frequently required organizations deemed to have significant deficiencies in their compliance program infrastructure to, as a condition of their CIAs, hire independent compliance experts to the company's board of directors or other governing body. The independent expert must, among other things, perform biannual or other periodic reviews of the company's compliance program according to a predetermined work plan. These reviews are designed to comprehensively evaluate the effectiveness of the organization's compliance function and associated opportunities for improvement, as well as aid the company's governing body in fulfilling their fiduciary duties with respect to compliance program oversight.

Notably, HHS-OIG has not updated its industry-specific compliance program guidance documents in approximately 15 years. However, the importance of periodically testing, reevaluating, and modifying a company's compliance program to ensure its efficacy was reinforced through HHS-OIG's March 2017 "Measuring Compliance Program Effectiveness: A Resource Guide," developed jointly with the Health Care Compliance Association (HCCA) (the HHS-OIG/HCCA

Resource Guide). Like the recently updated DOJ Guidance, the HHS-OIG/HCCA Resource Guide recognizes that there is no one-size-fits-all formula for assessing the effectiveness of a compliance program, that the guidance should not be applied as a rigid "checklist," and that using all or even a large number of the metrics suggested "is impractical and not recommended." Moreover, the importance of maintaining a progressive compliance function that is responsive to changing organizational needs and priorities features prominently in the HHS-OIG/HCCA Resource Guide as well.

For instance, mirroring the "lessons learned" concept in the updated DOJ Guidance, the HHS-OIG/HCCA Resource Guide suggests that key policies implicated by an investigation or compliance issue should be reviewed to address any potential ambiguities, complexities, or missing safeguards. The HHS-OIG/HCCA Resource Guide also similarly reinforces the importance of auditing the information flow from business units to the compliance department for purposes of developing the organization's risk assessment. Finally, the HHS-OIG/HCCA Resource Guide, like the DOJ Guidance, encourages use of various mechanisms to evaluate employees' perceptions of the compliance function, understanding of compliance training, and ability to effectively utilize the company's internal mechanisms for disclosing compliance issues.

Recommendations to Keep Your Compliance Program Fresh

In light of these DOJ and HHS-OIG policies, the federal government

is increasingly and unmistakably signaling to healthcare and life sciences organizations that having a compliance program that merely “checks the boxes” on the seven essential elements is insufficient. Rather, to help stay out of the government’s crosshairs in the first instance, and satisfy regulators’ expectations in the event of an investigation, companies must ensure that their compliance programs are nimble, with the ability to self-monitor and adapt to changed circumstances.

To put your organization in the best possible position should there be an enforcement action, following are a few key areas to focus on and devote resources to:

• **Use of Data Analytics & Industry Trends:** Healthcare and life sciences organizations should consistently analyze and review internal operational data, hotline complaints, past auditing trends or significant findings, and recent enforcement activity in their respective industry sectors to inform determinations about the areas of greatest risk to the organization. Such analyses can both guide decision-making about resource allocation and prioritization of compliance activities, as well as drive real-time targeted updates to the organization’s policies and procedures, training, and other compliance activities. Given both DOJ’s and HHS-OIG’s heightened emphasis on data analytics, healthcare organizations also should ensure compliance personnel have the authority to request and obtain such data to evaluate risk areas, either indirectly (e.g., through reports to the

company’s management-level compliance committee) or directly from the applicable business departments.

• **Audit Compliance Program Infrastructure:** Consistent with the themes articulated in the DOJ Guidance and longstanding pronouncements from HHS-OIG, healthcare and life sciences companies should also periodically test their compliance policies, procedures, processes, and systems to ensure they are functioning optimally and as intended. The evaluation should focus largely on specific, measurable, and meaningful *outcomes*, as opposed to numerical *outputs* (g., percentage of employees receiving compliance training, number of audits conducted, number of investigations closed). Looking at outcomes — for example, evaluating the effectiveness of compliance training based on incident logs or spot-checking to ensure hotline complaints were timely documented, responded to, investigated, and resolved consistent with policy — typically provides a more useful picture of whether the compliance program is working appropriately.

• **Conduct Employee Surveys:** Employee surveys feature prominently in both the DOJ Guidance and HHS-OIG/HCCA Resource Guide as a tool to measure compliance program effectiveness. Healthcare and life sciences organizations should consider utilizing surveys to gauge the compliance culture, evaluate the strength of the company’s controls, and solicit input on new or evolving risk areas and challenges that may necessitate

revisions to the compliance program. Surveys may effectively be utilized to test employees’ knowledge of the compliance program infrastructure (g., where to access relevant resources, identity of the compliance officer), as well as perceptions of compliance matters (e.g., what the company is doing to drive compliance culture, whether the training is useful to employees in performing their day-to-day job duties).

Conclusion

The DOJ and HHS-OIG policies and practices outlined here demonstrate that the government will continue to insist that healthcare companies establish, maintain, and periodically test the efficacy of their compliance programs. Programs that are tailored to a company’s business and personnel and adaptable to changes and trends are more likely to ensure that those companies remain on the right side of government investigations of fraud and abuse, or, in the event of such investigations, mitigate risk and costs to the organization.

