

Client Alert

Healthcare Practice Group

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Compliance 2.0 and the Significance of HHS OIG's 2017 Resource Guide: "Measuring Compliance Program Effectiveness"

I. INTRODUCTION

On March 27, 2017, in conjunction with the Health Care Compliance Association ("HCCA") annual Compliance Institute ("CI"), the Department of Health and Human Services ("HHS"), Office of the Inspector General ("OIG") released *Measuring Compliance Program Effectiveness: A Resource Guide* ("Resource Guide"), which outlines a wide range of concrete ideas for contemplating ways in which various components of a corporate compliance program can be benchmarked and measured.

The Resource Guide emanated from a collaborative session during a roundtable on January 17, 2017 in Washington, D.C. where seasoned compliance personnel and OIG representatives met to specifically explore methods of assessing and measuring key compliance program elements and functions. The roundtable format allowed for the sharing of ideas with the expectation that those ideas would subsequently be aggregated into a resource to provide ideas for compliance program evaluation and enhancement. Importantly, the Resource Guide is *neither a "standard" nor designed to be a checklist* and, in fact, the Resource Guide acknowledges the impracticality of using all or even a large number of the measurement options.

OIG issued the Resource Guide on the same day that Inspector General ("IG"), Daniel Levinson, the longest tenured HHS IG in history, presented the keynote address during the 21st annual HCCA CI which has become akin to an annual tradition as the IG's presentation is very much anticipated by conference attendees. During his 2017 CI remarks, the IG confirmed the OIG's renewed focus on compliance program effectiveness and the importance of assessing effectiveness so that programs are continuously maturing.

In this manner, the Resource Guide echoes a theme that has been articulated in several of the OIG's more recent guidance documents, including the April 2016 *Updated Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act*. In that guidance

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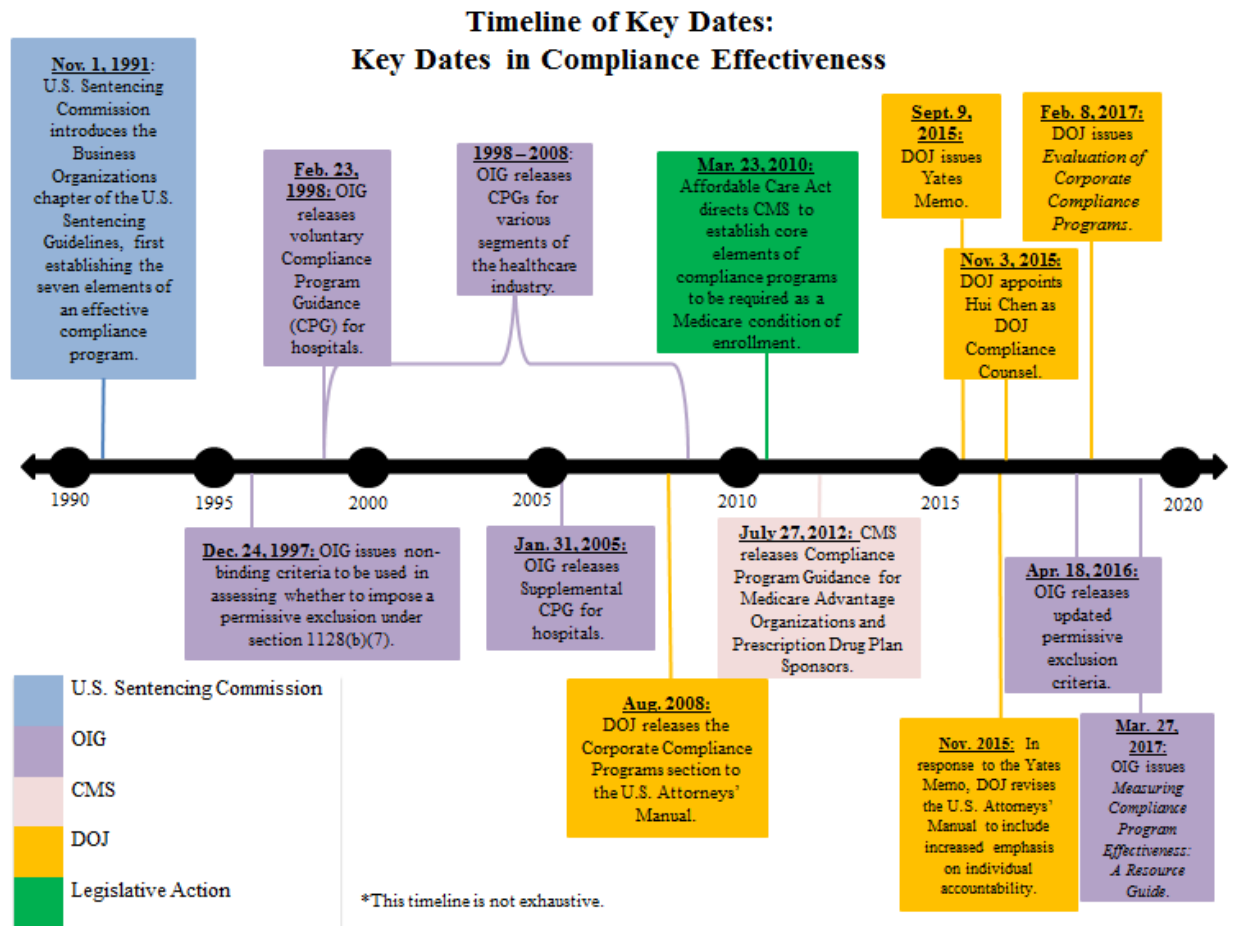
document, OIG updated a 1997 summary of non-binding factors that the agency considers when determining whether to exercise its permissive authority to exclude organizations and individuals from participation in federal healthcare programs. In the 2016 issuance, OIG makes clear that the existence of a compliance program that incorporates the seven elements of an effective compliance program as articulated in US Sentencing Guidelines **does not affect the risk assessment**. Said differently, there are no bonus points for implementing a compliance program. Instead, an organization is expected to operate a compliance program and must demonstrate characteristics of a more advanced compliance program, such as voluntary disclosures and effective remediation plans, in order to receive “lower risk” consideration.¹

The renewed focus on compliance program effectiveness along with enhanced expectations for those programs was effectively described by the IG as “**Compliance 2.0**” and the OIG is not alone in this endeavor. In February of 2017, the U.S. Department of Justice (“DOJ”), Criminal Division, Fraud Section issued a guidance document *Evaluation of Corporate Compliance Programs* (“DOJ Compliance Effectiveness Guidance”). In the DOJ Compliance Effectiveness Guidance, the DOJ outlines important topics and common questions that DOJ will pose when investigating a corporate entity. As the DOJ Compliance Effectiveness Guidance is dissected, it becomes clear that organizations that have not implemented sound compliance programs will have a far more challenging time answering questions on the topics outlined in the DOJ Compliance Effectiveness Guidance.

All said, while it is important to understand that the specific purpose of the Resource Guide is to provide examples of potential approaches to measuring the effectiveness of certain elements of a compliance program for organizations of varying size, operational complexity and resources, the issuance is part of a larger compliance and enforcement picture and is most appropriately viewed as an important detail of a larger developing “Compliance 2.0” framework. This Client Alert explores the latest compliance program effectiveness issuance by OIG.

II. ENHANCED FOCUS ON COMPLIANCE PROGRAM EFFECTIVENESS

As noted, the OIG’s Resource Guide is the latest development in the compliance program effectiveness arena. Over approximately the last 30 years, the U.S. Sentencing Commission, the Centers for Medicare & Medicaid Services (“CMS”), OIG, and DOJ have all contributed to this area and have recommended, in some form, that compliance program “effectiveness” be measured. Below we highlight some of these key industry developments.



III. OVERVIEW OF OIG RESOURCE GUIDE

In light of this history, OIG’s desire to provide more concrete guidance to providers on compliance program effectiveness is understandable. Importantly, the Resource Guide recognizes that compliance programs are not one-size-fits-all and that the tools used for measuring effectiveness will vary based on the organization’s size, operational complexity, industry sector, and resources. Specifically, the Resource Guide states that “[a]ny attempt to use this as a standard of a certification is discouraged by those who worked on this project; one size truly does not fit all.”

The Resource Guide lists individual program metrics, noting that “the purpose of this list is to give health care organizations as many ideas as possible, be broad enough to help any type of organization, and let the organization choose which ones best suit its needs.” The Resource Guide emphasizes that this list is not a “checklist” that should be “applied wholesale to assess a compliance program.” Indeed, the Resource Guide notes that using all of the compliance metrics, or even a large number, “is impractical and not recommended.” Rather, the Resource Guide indicates that organizations “may choose to use only a small number of these in any given year” and are free to choose the metrics that best suit the organization’s needs.

The Resource Guide is structured to provide tools regarding both “**what to measure**” and “**how to measure**” with respect to the following seven elements of a compliance program first established by the U.S. Sentencing Guidelines Manual:

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors and Other Agents
4. Communication, Education, and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems
6. Discipline for Non-Compliance
7. Investigations and Remedial Measures

IV. RECURRING THEMES AND KEY TAKEAWAYS

As noted, as various government agencies’ positions on compliance program expectations continue to develop, several recurring themes have been emphasized across the enforcement community. Unsurprisingly, the Resource Guide builds on these themes by providing more tangible ideas for providers seeking to operationalize these concepts.

a. Compliance Culture

What to Measure: The Resource Guide emphasizes that OIG expects that an organization with an effective compliance program will have a culture of compliance with significant support and involvement from its board and senior leadership. The Resource Guide also focuses on the resources provided for the organization’s compliance program, including budget and appropriate staffing.

How to Measure: The Resource Guide suggests that organizations may want to interview members of their board to evaluate whether they understand their role and responsibilities relating to compliance and also may want to establish specific compliance competencies for members of its board. (Measures 2.2 and 4.32).

The Resource Guide includes a number of measures designed to evaluate the qualifications of the compliance officer and the compliance officer’s stature in the organization. For example, the Resource Guide includes measures relating to the certifications (such as a Certification in Healthcare Compliance) held by the compliance officer, whether the compliance officer is a key stakeholder in the organization’s strategic initiatives, how the compliance officer’s reporting structure reflects his or her independence, and the authority of the compliance officer to engage outside legal counsel or to initiate a working group (Measures 2.21 – 2.32). Additionally, the Resource Guide suggests that organizations may want to survey employees to gauge, among other things, their perceptions of the compliance officer role. (Measure 2.31). The Resource Guide also probes the compliance officer’s authority to intervene in certain circumstances to, for example, implement a bill hold. (Measure 7.39).

The Resource Guide stresses the need to examine the budget and other resources provided to the compliance department and assess whether they are adequate to handle the organization’s risk profile. For example, the Resource Guide indicates organizations may want to evaluate the ratio of the compliance department’s full time employees as compared to business functions, as well as the compensation for compliance employees when compared to business employees. (Measures 2.33 and 2.38).

Trends Across Other Compliance Guidance Issuances: The importance of senior leadership’s support for and involvement in compliance is a common theme repeatedly emphasized by OIG and DOJ. For example, in April 2015, OIG, in collaboration with HCCA and other industry organizations, released guidance regarding the board’s role in compliance efforts. OIG has also incorporated management certifications and board resolutions into its new Corporate Integrity Agreement (“CIA”) model to signal, among other things, that compliance is not solely the responsibility of the compliance officer. Additionally, in certain instances, OIG has included an obligation in CIAs that the organization engage a compliance expert to provide the board with a report regarding the effectiveness of the organization’s compliance program.

The DOJ Compliance Effectiveness Guidance also emphasized the board and management’s support for compliance. Specifically, the DOJ Compliance Effectiveness Guidance instructs prosecutors to consider the following in making prosecutorial decisions: actions of senior leadership, the compliance expertise and information made available to the board, and the funding and resources devoted to compliance. Also, during a roundtable at the New York University (“NYU”) Program on Corporate Compliance and Enforcement, DOJ’s Compliance Counsel Hui Chen discussed the importance of senior leadership’s involvement and support of compliance efforts and indicated that what the DOJ wants to “see is real attention, real dialogues, and also executives really walking the walk beyond talking the talk.”

a. Self-Evaluation and Risk Assessments

What to Measure: Numerous measures included in the Resource Guide seek to probe whether a compliance program is a mere static “paper program” or whether it is an evolving, highly functioning program that reflects on the effectiveness of its compliance efforts and engages in an assessment of the organization’s risk.

How to Measure: Healthcare organizations should seek to ensure that they are doing more than “going through the motions” on compliance. For example, the Resource Guide indicates it is not enough merely to have policies and procedures. Rather, an effective compliance program may take steps to evaluate whether such policies and procedures are actually accessed by stakeholders (through monitoring “hits”) and may interview the staff charged with following such policies to ensure they can articulate the policy’s requirements. (Measures 1.2 and 1.27).

Sometimes referred to within the industry as the eighth element of an effective compliance program, risk assessments are an important component of the Resource Guide. The Resource Guide indicates programs should examine its risk assessment process in a variety of ways including who participates, how topics are prioritized, how mitigation steps are determined, and how the risk assessment assists in the work plan creation process. (Measures 5.27 – 5.36).

Trends Across Other Compliance Guidance Issuances: Over the past several years, OIG has begun including a requirement for a formal risk assessment and internal review process in CIAs. Risk assessment efforts were also highlighted in the DOJ Compliance Effectiveness Guidance, which indicates that prosecutors should consider the organization’s risk management processes in its investigations of corporate entities. Also, CMS’s mandatory Compliance Program Guidelines for Medicare Advantage Organizations and Prescription Drug Plan Sponsors include requirements relating to the development of a system to identify compliance risks.ⁱⁱ

b. Self-Policing and Self-Disclosure

What to Measure: The Resource Guide emphasizes that effective self-policing and self-disclosure help demonstrate the effectiveness of a compliance program.

How to Measure: The Resource Guide includes a number of measures regarding the organization’s internal investigations and audit processes. For example, the Resource Guide includes questions regarding whether there are written guidelines for self-disclosures and whether such guidelines address the information to be shared with regulators. (Measure 7.42).

The Resource Guide indicates that questions such as “who, what, when, and how” should be answered in every investigation and reflected in the organization’s investigation files. (Measure 7.5). Further, the Resource Guide suggests that organizations consider conducting “devil’s advocate” mock presentations to probe how a regulator might view the organization’s investigation and remediation process. (Measure 7.12, Measure 7.63). In such instances, an in-house attorney may act as a government entity. (Measure 7.63).

The Resource Guide also suggests that organizations assess adherence to the 60-day overpayment rule by reviewing incident tracker documentation and that organizations may want to review a sample of five investigation files to evaluate the thoroughness of their files. (Measures 5.2, 5.8).

Trends Across Other Compliance Guidance Issuances: Self-policing and self-disclosure are important themes reiterated across the government. The DOJ Compliance Effectiveness Guidance indicates that DOJ considers the type of information or metrics the company collected and used to aid in detecting the misconduct and how this information has “informed the company’s compliance program” in its enforcement decisions.

Past statements from OIG have also emphasized the importance of self-policing and self-disclosure. In his keynote address at the 20th Annual HCCA CI on April 18, 2016, IG Daniel R. Levinson observed that:

When self-disclosure is involved—when again that self-correcting goes on by our institutions—that is taken note of. That is important. There is a presumption that exclusion would not be necessary under those circumstances. . . . Self-correcting and self-disclosing means that there is going to be a much wider understanding by OIG about how to approach the exclusion authorities that we have and assurance that those healthcare institutions that are able to self-correct are given the leeway, are given the room, to be able to do the self-correction without further imposition of obligations by OIG.

Hopefully, the government’s emphasis on self-disclosures signals recognition that disclosing misconduct does not necessarily suggest deficiencies in an organization’s compliance program but, rather, can be the mark of an effective compliance program.

c. Screening and Third-Party Relationships

What to Measure: The Resource Guide emphasizes robust screening efforts for employees, vendors, medical staff, and others. Not only should such screenings be frequent, OIG emphasizes that screenings should be more than merely going through the motions.

How to Measure: The Resource Guide’s measures include an evaluation of how broad screening searches are constructed (e.g., do the search parameters include maiden names and aliases). (Measure 3.10). Also, the Resource Guide indicates an organization should consider its policies and procedures regarding the investigation of potential “hits” on screening lists. (Measures 3.21 and 3.31).

The Resource Guide discusses high risk screening processes that may be used to identify high risk positions within the organization (such as clinicians working with children or mental health patients or handling cash)

that may require additional screening efforts (such as fingerprinting, financial background checks, etc.). (Measure 3.26).

Throughout the Resource Guide, OIG suggests that providers should consider their oversight efforts for vendors and other third parties. The Resource Guide suggests that an organization take steps such as auditing vendors and other third parties to ensure the vendors and third parties have documented evidence of required compliance training and orientation to the organization's (*not* the vendor or third party's) code of conduct and applicable compliance policies and procedures. (Measure 3.33). The Resource Guide also indicates that healthcare organizations may want to seek certifications from vendors and other third parties to ensure such parties have complied with screening expectations. (Measure 3.34). Additionally, organizations should consider the consequences for vendors who fail to comply with compliance program expectations. (Measure 5.77).

Of note, the OIG also suggests that organizations may want to conduct exit-type interviews of vendors and other third parties to evaluate their understanding of the organization's compliance program. (Measure 3.24). The Resource Guide suggests that the compliance department evaluate its knowledge of contracts with business partners and have access to an inventory of the organization's business partners. (Measure 5.21).

Trends Across Other Compliance Guidance Issuances: Notably, third-party management was also a focus of the DOJ Compliance Effectiveness Guidance, indicating that enforcement entities may be signaling that healthcare organizations may be held accountable for misconduct committed by third parties. The DOJ Compliance Effectiveness Guidance outlined certain key considerations regarding third-party management such as: (a) the business rationale for using third parties, (b) how the company analyzed the third party's incentive model against its compliance risks, and (c) the manner in which the company monitored its third parties.

Additionally, CIAs typically require that the CIA-obligated provider train, screen, and distribute applicable policies and procedures and codes of conduct to any vendors or third-parties included within the scope of the CIA.

d. Individual Accountability and Employee Incentives

What to Measure: The Resource Guide focuses on how an organization handles individual misconduct and how it incentivizes compliant behavior. The Resource Guide suggests that an organization's internal investigative process pay "special attention" to individual accountability. (Measure 7.3).

How to Measure: To evaluate these compliance efforts, OIG suggests probing the process for disciplining employees for misconduct, including an evaluation of the compliance officer's input into disciplinary action decisions. (Measure 6.3). An effective compliance program may also distribute high-level results of disciplinary action in order to better inform employees regarding the consequences of misconduct. (Measure 6.21).

OIG suggests that disciplinary action should not just be limited to perpetrators of the misconduct. For example, disciplinary action may need to encompass individuals who failed to report issues or who caused misconduct to occur. (Measures 6.29, 6.30).

In addition to disciplining misconduct, the Resource Guide notes that an effective compliance program seeks to incentivize compliant behavior through various mechanisms, such as incorporation of compliance into promotion criteria and performance reviews. (Measures 6.32-6.34). Of note, the Resource Guide suggests that

organizations consider whether the head of compliance participates in performance reviews of senior executives. (Measure 6.33).

Regarding internal investigations, the Resource Guide includes an evaluation of whether the organization's baseline investigative plan outlines the communication approach for interviewing current and prior employees and whether there are appropriate protections for people being interviewed. (Measure 7.3). In light of this and other recent developments regarding *Upjohn* warnings in internal investigations,ⁱⁱⁱ organizations may want to revisit their approaches to employee interviews.

Trends Across Other Compliance Guidance Issuances: The Resource Guide's emphasis on individual accountability is not surprising given the focus on individual accountability as signaled through DOJ's issuance of the Yates Memo and recent DOJ and OIG enforcement actions against individuals. Additionally, recent CIAs have required that certain members of senior management annually execute a certification indicating that, to the best of the individual's knowledge, the organization is in compliance with applicable federal healthcare program and CIA requirements.

V. CONCLUSION

Building upon prior issuances from OIG, DOJ and other government entities, the Resource Guide refocuses providers on the traditional seven elements of an effective compliance program and offers practical tools for healthcare organizations seeking to evaluate their compliance program's effectiveness. Although intended as a resource for healthcare organizations, concepts from the Resource Guide have broad application and may also assist organizations across various industries in evaluating their corporate compliance programs. Given the numerous recent developments in this area, it may be prudent for healthcare and other types of organizations to consider how they would best demonstrate their compliance program's effectiveness (and their efforts to measure effectiveness) if scrutinized by a third party.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice. In some jurisdictions, this may be considered "Attorney Advertising."

ⁱ IG Daniel R. Levinson explained OIG's position on April 18, 2016 at last year's HCCA CI, stating: "Compliance has become such a mature exercise that it is presumed that healthcare institutions . . . will have robust compliance programs. So that is assumed. One does not get bonus points for having a compliance program at this point. This is not new. This is well-established."

ⁱⁱ See Prescription Drug Benefit Manual, Chapter 9, § 50.6.2, Medicare Managed Care Manual, Chapter 21 § 50.6.2.

ⁱⁱⁱ See *Commonwealth v. Curley*, 131 A.3d 994, 1007 (Super. Ct. Pa. 2016) (finding that general counsel for Pennsylvania State University breached attorney-client privilege by disclosing information to a grand jury learned through an internal investigation when Penn State employees had not received a sufficient *Upjohn* warning); *Commonwealth v. Spanier*, 132 A.3d 481, 498 (Super. Ct. Pa. 2016) (same); *Commonwealth v. Schultz*, 133 A.3d 294, 299 (Super. Ct. Pa. 2016) (same).