

The OIG's Resource Guide: An Important New Tool for Measuring Compliance Program Effectiveness

PG Briefing, June 2017

Physician Organizations and Hospitals and Health Systems Practice Groups

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The recent publication, *Measuring Compliance Program Effectiveness: A Resource Guide* (Resource Guide), of the U.S. Department of Health and Human Services Office of Inspector General (OIG) and the Health Care Compliance Association (HCCA), represents another key development suggesting a dramatic shift in the practice of health care compliance. For years, health care providers were encouraged to maintain effective compliance programs, but providers had few sources of published guidance or objective criteria to consider when determining whether their compliance programs were effective in meeting their goals. The Resource Guide helps fill that gap and then some. The publication of the Resource Guide reinforces that government investigators will no longer simply inquire about the basic elements of the providers' compliance programs and their general activities when determining whether organizations should receive consideration for more favorable settlements or cooperation credit in the event of criminal prosecutions. Instead, providers can anticipate that investigators will routinely ask them to demonstrate how they measured their compliance programs' effectiveness and improved elements of their programs, if and when necessary, to further protect against fraud, waste, and abuse. If health care providers don't want to be tomorrow's next major enforcement headline, they should act now to ensure that their compliance programs are effective.

Long before publication of the Resource Guide, the OIG outlined a seven-part framework, known as the Seven Elements of an Effective Compliance Program, or simply the "Seven Elements," that health care providers could use as the basis for establishing and maintaining their compliance programs. The Seven Elements generally charge the compliance program, through the compliance officer, with developing policies, receiving complaints, auditing and monitoring conduct, and appropriately responding to acute or systemic compliance concerns.¹ The Seven Elements do not themselves, however, focus on measuring the effectiveness of the compliance program itself.

¹ Office of Inspector General, *Publication of the OIG Compliance Program Guidance for Hospitals*, 63 Fed. Reg. 8987, 8989 (Feb. 23, 1998) (hereinafter Hospital CPG).

With the publication of the Resource Guide, taken in conjunction with other recent developments in the U.S. Federal Sentencing Guidelines (Sentencing Guidelines) and guidance published by the Department of Justice (DOJ), health care providers should be prepared to objectively demonstrate that their compliance programs are effective in meeting their goals. Measuring compliance program effectiveness and making changes to improve the program can be achieved by using components of the Resource Guide. This Briefing proceeds in three parts. In Part One, we discuss the historical development of the Seven Elements to provide compliance professionals with a solid background of how effective compliance programs can provide benefit in the event of investigations. Part Two discusses the suggestion that organizations on a regular basis objectively measure the effectiveness of their compliance programs and explains that, in light of the existing guidance, including the Resource Guide, federal enforcement agencies are likely to expect that, at a minimum, providers' compliance programs will be subject to ongoing evaluation and improvement. Part Three explains the significance of these new expectations and recommends how health care providers can ensure that their compliance programs remain effective in proactively evaluating, measuring, and improving their compliance with relevant health care laws and regulations.

Part One: Development of the “Seven Elements” of an Effective Compliance Program

It would be difficult to understand the importance of the Resource Guide without first taking account of the pre-existing guidance regarding the development and operation of health care compliance programs. As further described below, providers will find the most useful health care industry-specific guidance in the various compliance resources published by the OIG. These documents have their roots in the Sentencing Guidelines, published in 1991, which created a framework for the criminal sentencing of organizations. The Sentencing Guidelines offer organizations an opportunity to receive lighter sentences for criminal violations if, prior to the violation, the organizations

developed compliance programs that met seven distinct elements.² While these elements underwent some changes when the OIG adopted them in the health care context in the form of the Seven Elements, for nearly three decades, the seven criteria set forth in the Sentencing Guidelines have served as the basic framework for compliance programs across all industry sectors.

In 1997, six³ years after the publication of the Sentencing Guidelines, the OIG began publishing a series of Compliance Program Guidance documents (CPGs) for health care organizations. Taken together, these CPGs are the fundamental authoritative guidance on health care compliance programs. In the absence of a government-approved model compliance program for health care providers to rely on, the Seven Elements are the most reliable guide for providers to use when establishing effective health care compliance programs.

Federal Sentencing Guidelines for Organizations

The Sentencing Reform Act of 1984⁴ provides authority to the U.S. Sentencing Commission (Commission) to publish and update the Sentencing Guidelines, which may be considered⁵ when imposing sentences for violations of federal criminal law.⁶ Health care providers that violate criminal fraud and abuse laws, including the Anti-Kickback Statute⁷ or the Criminal False Claims Act,⁸ could find themselves directly impacted by the Sentencing Guidelines in the event of a criminal investigation.

² U.S. Sentencing Commission, *1991 Federal Sentencing Guidelines Manual*, p. 352, § 8A1.2, Application Note (k) (hereinafter 1991 Sentencing Manual), available at http://www.ussc.gov/sites/default/files/pdf/guidelines-manual/1991/manual-pdf/Chapter_8.pdf (last accessed Apr. 26, 2017).

³ The OIG made a first attempt at publishing provider-specific guidance in 1997 with its publication of a Model Compliance Plan for Clinical Laboratories, 62 Fed. Reg. 9435 (Mar. 3, 1997). In 1998, after the OIG published guidance documents for hospitals (the Hospital CPG) and home health systems (63 Fed. Reg. 42410, Aug. 7, 1998) utilizing a more streamlined framework, OIG published an updated guidance document for clinical laboratories that superseded the 1997 guidance and utilized this revised framework.

⁴ Pub. L. No. 98-473, 98 Stat. 1987 (1984).

⁵ Pursuant to *United States v. Booker*, 543 U.S. 220 (2005), the Sentencing Guidelines are now advisory.

⁶ See generally United States Sentencing Commission, *Federal Sentencing: The Basics* (2015), available at http://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-projects-and-surveys/miscellaneous/201510_fed-sentencing-basics.pdf (last accessed Apr. 26, 2017).

⁷ 42 U.S.C. § 1320a-7b.

⁸ 18 U.S.C. § 287.

However, in describing steps that organizations can take to reduce their culpability in the event of criminal convictions, Chapter 8 of the Sentencing Guidelines also provides important benchmarks for providers seeking to establish effective compliance programs apart from the throes of criminal proceedings.

Those parts of the Sentencing Guidelines that are applicable to organizations have their roots in a 1991 recommendation to Congress in which the Commission proposed new rules for the sentencing of organizations.⁹ This proposal, which the Commission developed in conjunction with private defense attorneys, judges, probation officers, and academicians,¹⁰ represented the first binding framework for imposing criminal sanctions on organizations. Within this framework, the existence of an “effective program to prevent and detect violations of law” could reduce an organization’s culpability for an offense, therefore reducing its ultimate penalty.¹¹ To benefit from this provision, organizations must have implemented compliance programs that met seven specific criteria.¹² In addition, organizations that self-reported potential violations also could receive lighter sentences.¹³ Since following the steps outlined in the seven criteria was (and is still) likely to result in providers identifying violations of law before the violations became known to the government, these developments greatly incentivized the development of corporate compliance programs, especially in heavily regulated industries such as health care.

In 2004, the Commission strengthened the criteria that organizations must follow to establish and maintain effective compliance programs. The 2004 amendment generally sharpened the Sentencing Guidelines’ focus on internal controls and, in effect, brought the seven criteria in the Sentencing Guidelines closer to the OIG’s Seven Elements, which were first established in the 1998 Compliance Program Guidance for Hospitals (Hospital CPG) as further described below.¹⁴ For example, the 1991 Sentencing

⁹ U.S. Sentencing Commission, *Supplementary Report on Sentencing Guidelines for Organizations 1* (Aug. 30, 1991), available at <http://www.ussc.gov/sites/default/files/pdf/training/organizational-guidelines/historical-development/OrgGL83091.pdf> (last accessed Apr. 20, 2017).

¹⁰ *Id.* at 2.

¹¹ 1991 Sentencing Manual, p. 364, § 8.C2.5(f).

¹² 1991 Sentencing Manual, p. 352, § 8A1.2, Application Note (k).

¹³ *Id.* at § 2.5(g).

¹⁴ Hospital CPG, 63 Fed. Reg. at 8989.

Guidelines required that “specific individual(s) within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with” compliance standards and procedures. The 2004 amendment went a step further and required organizations to designate *one* high-level official with “overall responsibility” for the compliance program; furthermore, that official must “be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.”¹⁵ These requirements closely match the OIG’s recommendation, repeated throughout the CPGs, that organizations designate a chief compliance officer with adequate resources to oversee the compliance program and with governing board reporting responsibilities.¹⁶

In 2010, the Commission added an application note to the Sentencing Guidelines that clarifies “an organization should assess [its] compliance and ethics program and make modifications necessary to ensure the program is effective.”¹⁷ The 2010 amendment also encourages “the use of an outside professional advisor to ensure adequate assessment and implementation of any modifications.”¹⁸ It also clarifies that a person will only be considered to have “direct reporting obligations” to the organization’s governing board “if the individual has express authority to communicate personally to the governing authority promptly on any matter involving criminal conduct or potential criminal conduct and no less than annually on the implementation and effectiveness of the compliance and ethics program.”¹⁹ The evolution of these latter updates was once again similar to the OIG’s earlier recommendations with respect to compliance officers.²⁰

Today, Chapter 8, Section B2.1 of the Sentencing Guidelines provides detailed guidance on the characteristics of effective compliance programs. To receive any credit

¹⁵ U.S. Sentencing Commission, *Amendments to the Sentencing Guidelines*, 109-12 (May 10, 2004), available at http://www.ussc.gov/sites/default/files/pdf/amendment-process/reader-friendly-amendments/20040430_RF_Amendments.pdf (last visited Apr. 27, 2017).

¹⁶ Hospital CPG, 63 Fed. Reg. at 8993.

¹⁷ U.S. Sentencing Commission, *Amendments to the Sentencing Guidelines*, 31 (May 3, 2010), available at http://www.ussc.gov/sites/default/files/pdf/amendment-process/reader-friendly-amendments/20100503_RFP_Amendments.pdf (last visited Apr. 27, 2017).

¹⁸ *Id.*

¹⁹ *Id.* at 31-32.

²⁰ Hospital CPG, 63 Fed. Reg. at 8993.

under the guidelines, an organization's compliance program must be "reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct."²¹ While the health care-specific legacy of the Sentencing Guidelines is that they form the backbone of the OIG's guidance with respect to effective health care compliance programs, providers also are encouraged to look to the direct reporting requirements established in 2004 as a best practice for the authority of their own compliance officers. Further, the 2010 amendment directly supports the contention that ongoing self-assessment is a crucial component of an effective compliance program.

OIG's Compliance Program Guidance Documents

Since 1997, the Industry Guidance Branch of the OIG has published and updated CPGs with the goal of encouraging providers to implement compliance programs rooted in industry best practices.²² To date, the OIG has released 15 CPGs covering 12 different health care provider types.²³ Each CPG embraces the Seven Elements as an appropriate framework for developing a compliance program for the provider type that it addresses. The Seven Elements for the health care industry as set forth in the CPGs are as follows:

1. Development and distribution of written standards of conduct, as well as written policies and procedures that promote the organization's commitment to compliance (e.g., by including adherence to compliance as

²¹ U.S. Sentencing Guidelines, Ch. 8, § B2.1(b) (2015).

²² E.g., Office of Inspector General, *Publication of the OIG Model Compliance Plan for Clinical Laboratories*, 62 Fed. Reg. 9435 (Mar. 3, 1997).

²³ OIG has released CPGs for: clinical laboratories (first released in 1997 with an update in 1998), hospitals (released in 1997 with a supplement in 2005), home health agencies (1998), third-party medical billing companies (1998), durable medical equipment prosthetics, orthotics, and supplies suppliers (1998), hospice providers (1999), Medicare + Choice organizations (1999), nursing facilities (first released in 2000 with a supplement in 2008), individual and small group physician practices (2000), ambulance suppliers (2003), pharmaceutical manufacturers (2003), and recipients of Public Health Service (PHS) research awards (2005). Each CPG is available at <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>. We note that the CPG covering recipients of PHS research awards was released in draft form only and never finalized.

an element in evaluating managers and employees) and that address specific areas of potential fraud;

2. Designation of a chief compliance officer and other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility of operating and monitoring the compliance program, and who report directly to the chief executive officer and the governing body;
3. Development and implementation of regular, effective education and training programs for all affected employees;
4. Maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;
5. Development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, and regulations of federal health care program requirements;
6. Use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem area[s]; and
7. Investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

The OIG first adopted the Seven Elements in the Hospital CPG, which continues to be significant because its broad approach to, and discussion of, compliance programs and risk areas are informative for health care provider types across the health care industry. As the OIG acknowledges, the Seven Elements set forth in the Hospital CPG “can be incorporated into the managerial structure of multi-hospital and integrated delivery systems.”²⁴ Thus, if a large, health care-focused organization finds that there is no specific CPG applicable to its business practices and structure—which is almost inevitable in the ever-changing health care industry—the Hospital CPG can nevertheless serve as a useful guide for compliance program effectiveness.

²⁴ Hospital CPG, 63 Fed. Reg. at 8989.

The Hospital CPG is structured around the Seven Elements, addressing each one in significant detail. Additionally, it specifically discusses a number of risk areas of broad application across the industry. The format the OIG used in the Hospital CPG proved to be successful and was adopted for subsequent CPGs. Providers to whom a CPG directly applies can expect that the CPG takes into account the idiosyncrasies of their role in the industry when discussing the Seven Elements. Additionally, the in-depth discussion in the CPGs of risk areas faced by such providers remains insightful.

Finally, the Hospital CPG directly acknowledges a key feature of the practice of health care compliance: that CPGs are not to be read in isolation. For example, in addressing laboratory billing requirements, the Hospital CPG refers readers back to the Model Compliance Program for Clinical Laboratories that the OIG published in 1997.²⁵ Thus, when addressing a potential compliance concern, compliance professionals are encouraged to understand how distinct service lines may be addressed in other CPGs.

While the Hospital CPG generally is considered the “gold star” model for compliance programs, the OIG has periodically recognized that smaller providers may have more limited resources such that establishment of full-scale compliance programs would be infeasible.²⁶ In this light, the OIG has emphasized that a step-by-step incremental approach may be used when developing and implementing voluntary compliance programs.²⁷ Specifically, the OIG encourages small providers to best prioritize their resources and implement components of the Seven Elements that are most relevant to them and most likely to identify and prevent fraud, waste, and abuse.

Part Two: Compliance Program Effectiveness: A Growing Focus for the OIG

As outlined in Part One, the OIG advises that health care compliance programs should be structured to meet the Seven Elements. However, the OIG specifically notes that “[s]uperficial programs that simply purport to comply with the elements discussed and

²⁵ *Id.* at 8991, n.29.

²⁶ See *generally* Physician Practice CPG, 65 Fed. Reg. 59434.

²⁷ *Id.*

described in this guidance or programs that are hastily constructed and implemented without appropriate ongoing monitoring will likely be ineffective and could expose [providers] to greater liability than no program at all.”²⁸ In other words, the OIG believes that compliance programs could be detrimental to providers if they do not perform effectively.

Thus, it should come as no surprise to health care providers that the OIG has increasingly turned its focus from what effective programs *look like*, to what providers are doing to ensure their programs are actually *effective*. While the OIG has touched on compliance program effectiveness in a number of CPGs, this focus was brought to the forefront most recently in March 2017 when the OIG published the Resource Guide. Recent complementary guidance from the DOJ in early 2017 also recognized that compliance programs should be routinely tested on effectiveness grounds to achieve and maintain their maximum potential for provider organizations.

The DOJ's 2017 FAQ

The DOJ plays a leading role in enforcing the health care fraud and abuse laws on behalf of the federal government. As such, the DOJ's pronouncements regarding compliance program effectiveness are important signals for providers to consider in how to best avoid becoming a target of this type of enforcement activity.

In early 2017, the DOJ released an informal guidance document entitled *Evaluation of Corporate Compliance Programs (2017 FAQ)*,²⁹ which provides a list of over 100 questions across numerous compliance program topical areas that federal investigators have found useful when evaluating allegations of provider fraud, waste, or abuse. Many of these questions focus on the organization's actions before and after the wrongful action occurred, which go hand-in-hand with the existence of an effective compliance

²⁸ Office of Inspector General, *Publication of the OIG Compliance Program Guidance for Home Health Agencies*, 63 Fed. Reg. 42410, 42411 (Aug. 7, 1998).

²⁹ Department of Justice, *Evaluation of Corporate Compliance Programs* (Feb. 8, 2017) (hereinafter 2017 FAQ), available at <https://www.justice.gov/criminal-fraud/page/file/937501/download> (last visited Apr. 30, 2017).

program. In the opening of the 2017 FAQ, the DOJ acknowledges that “the existence and effectiveness of the corporation’s pre-existing compliance program and the corporation’s remedial efforts to implement an effective corporate compliance program or to improve an existing one” are important factors when determining whether the organization will receive cooperation credit.³⁰

The 2017 FAQ does not give affirmative compliance guidance, but instead poses a series of inquiries that DOJ investigators “have frequently found relevant” when evaluating corporate compliance programs.³¹ The questions in the 2017 FAQ are divided into the following 11 categories:

1. Analysis and Remediation of Underlying Misconduct;
2. Senior and Middle Management;
3. Autonomy and Resources;
4. Policies and Procedures;
5. Risk Assessment;
6. Training and Communications;
7. Confidential Reporting and Investigation;
8. Incentives and Disciplinary Measures;
9. Continuous Improvement, Periodic Testing and Review;
10. Third-Party Management; and
11. Mergers and Acquisitions.

The 2017 FAQ highlights the federal government’s expectation that compliance programs must have clear accountability and support from senior leaders for the compliance function to be effective. As demonstrated by the 2017 FAQ’s questions focusing on senior and middle management, the government is interested in determining whether hospital leaders have established a culture of compliance within their organizations, and whether they themselves model behavior that reflects this type of culture. Other questions address whether the governing board has access to “compliance expertise” to help educate and navigate the organization through

³⁰ *Id.* at 1.

³¹ *Id.*

compliance challenges. The 2017 FAQ's focus on the compliance program's autonomy and resources shows that the DOJ considers a capable, autonomous compliance program, whose resources are appropriate in light of the organization's size and scope, to be a hallmark of an effective compliance function. Additionally, the broad focus of the questions—from board preparedness to analysis of third-party payment incentives—shows that the DOJ considers compliance to be a key concern at all levels of an organization. As such, an organization should ensure that its compliance program is poised to detect and respond to potential compliance concerns in a timely, appropriate manner, no matter where or at what level within the organization the concern first arose.

Importantly, many of the questions within the 2017 FAQ focus directly on assessing compliance program effectiveness. For instance, the Continuous Improvement, Periodic Testing and Review section asks, "How often has the company updated its risk assessments and reviewed its compliance policies, procedures, and practices? What steps has the company taken to determine whether policies/procedures/ practices make sense for particular business segments/subsidiaries?"³² Similarly, the section discussing Policies and Procedures asks, "Has the company had policies and procedures that prohibited the misconduct? How has the company assessed whether these policies and procedures have been effectively implemented? How have the functions that had ownership of these policies and procedures been held accountable for supervisory oversight?"³³ These questions, and others like them, demonstrate that the DOJ is interested in testing through these types of inquiries, for itself, whether the compliance program is truly effective. With the publication of the Resource Guide, the DOJ, the OIG, and other enforcement bodies now have an extensive set of sample criteria to structure these effectiveness determinations.

³² *Id.*

³³ *Id.* at 3.

The Resource Guide

In early 2017, the OIG convened a roundtable of health care compliance professionals and charged them with developing a framework for measuring the effectiveness of a compliance program.³⁴ The resulting document—the Resource Guide—is an extensive set of metrics that providers can use to help identify “what” and “how” to measure the effectiveness of nearly every aspect of their compliance programs. The Resource Guide is not intended to be a one-size-fits-all repeatable program for self-assessment. Rather, the metrics should be applied based on an organization’s particular risk areas, size, resources, and industry segment, any of which may change from year to year. As such, the OIG suggests that the utility of any one measure depends on the organization’s needs and recommends that organizations select a smaller number of measures for analysis that are practical and pertinent to their effectiveness reviews in any given year.³⁵ This is certainly comforting advice since the Resource Guide comprises 53 pages of material with over 650 separate individual effectiveness measures.

The Resource Guide is presented as a long series of “suggestions” on methods through which a compliance program’s effectiveness may be objectively assessed. The suggestions focus on the Seven Elements and are summarized below:

- *Standards, policies and procedures.* This section will help providers determine whether their compliance policies are accessible, and actually accessed, by affected parties. It also asks whether policies are high-quality documents developed with the input of key stakeholders and whether they are reviewed at appropriate intervals. Importantly, the questions in this section also will help providers verify that they have adopted a Code of Conduct that is understandable and relevant to all affected stakeholders and whether a formal compliance plan has been adopted and appropriately updated.

³⁴ Office of Inspector General, *Measuring Compliance Program Effectiveness: A Resource Guide*, at 2 (Mar 27, 2017), (hereinafter *Resource Guide*), available at <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf> (last accessed Apr. 20, 2017).

³⁵ *Id.* at 2-3.

- *Compliance program administration.* This section focuses on whether the compliance program is administered in a way that is appropriate for the size, resources, and scope of the provider. In particular, these metrics will help providers determine whether their governing bodies are actively engaged in the compliance program and promote a culture of compliance across all business functions of the provider. Additionally, this section asks whether the compliance program is appropriately resourced, whether the compliance officer has other operational responsibilities, and whether the compliance officer's reporting structure is sufficiently independent of other operations functions. Like the 2017 FAQ, the need for external outside expertise is addressed here to assist the organization in addressing compliance issues. Other questions focus on whether compliance considerations are included in all employees' performance evaluations, whether regular and appropriate risk assessments are conducted, and whether the role of legal counsel is appropriately defined with respect to the compliance program. Finally, this section inquires about both the frequency and substance of governing body compliance education and external reviews of the compliance program's effectiveness.
- *Screening and evaluation of employees, physicians, vendors, and other agents.* The analysis in this section focuses on whether all employees, physicians, vendors, and other agents are adequately screened against the OIG Exclusion List and other relevant government sanctions lists prior to their engagement. This includes whether the provider has designated one person or office as being responsible for performing such exclusions checks and has a protocol for responding to identified exclusion "hits." Another consideration is whether the provider has processes in place to identify and disclose conflicts of interest and whether employees, physicians, vendors, and other pertinent agents receive appropriate education on these conflicts. These metrics emphasize that the provider should remain vigilant regarding employee, physician, vendor, and other

agent eligibility both at the time of initial engagement and thereafter.

- *Communication, education, and training on compliance issues.* This section reviews whether the compliance program has established appropriate lines of communication throughout the provider organization. The identified measures will help providers assess whether their compliance training functions are accessible to all employees and whether they are written in a way that is comprehensible to all affected employees. Additionally, the inquiries measure whether the provider engages in targeted compliance training for high-risk employees, whether participation in these training sessions is tracked, and whether employees are held accountable for any lack of participation in these activities.
- *Monitoring, auditing, and internal reporting systems.* The criteria in this section focus on whether the compliance program has established adequate protocols for gathering relevant information regarding incidents of noncompliance. These methods include the establishment of confidential reporting mechanisms such as a hotline, and audits conducted internally and by outside experts to investigate allegations of noncompliance. The metrics prompt the provider to monitor how it responds to these reports, including incident tracking to ensure adherence to timely overpayment refunding requirements.³⁶ These criteria also inquire whether the provider has created its own annual compliance work plan, and whether the work plan has appropriately guided the compliance program's auditing and monitoring activities for the relevant period. In addition, this section addresses how the provider responds to audits (i.e., whether management is kept appropriately informed of the audit results and if effective corrective action plans are developed and followed thereafter).

³⁶ See, e.g., 42 C.F.R. § 401.305.

- *Discipline for noncompliance.* This section addresses whether the provider's policies on corrective action are effective and are followed consistently throughout the organization. They prompt the provider to assess whether appropriate parties are engaged in the corrective action process and whether its corrective action procedures are appropriately thorough. These considerations will assist providers in assessing whether their employees and associates are aware of the corrective action procedures, and whether incentive and promotion criteria are appropriately aligned with compliance priorities. Finally, this section emphasizes that an adequate documentary record should be maintained throughout the corrective action process.
- *Investigations and remedial measures.* The metrics in this section relate to whether providers respond appropriately to reported compliance concerns. Providers are prompted to evaluate their guidelines on conducting investigations, including those done through legal counsel under the attorney-client privilege and/or work product doctrine, and determine whether investigations are consistently conducted by appropriately trained, independent investigators, and whether those investigators properly document their actions. These considerations also will assist providers in determining whether their investigations lead to appropriate and effective remedial responses, including corrective action plans based on a root-cause analysis, and whether the providers follow through on these corrective action plans. Finally, these factors will help providers determine whether their third-party agreements obligate vendors to cooperate in investigations.

Providers engaging in a self-assessment are strongly encouraged to utilize the Resource Guide to identify key metrics that can aid in measuring the effectiveness of their own compliance programs. For example, to ensure that compliance program policies and procedures are having a real impact on their organizations, providers can audit how many actual "hits" are recorded on the review of such policies and

procedures.³⁷ On the other hand, organizations interested in assessing their overall culture of compliance can look to the job descriptions of management to ensure that they contain “concrete compliance deliverables other than training and abiding by the Code of Conduct.”³⁸ However, the Resource Guide suggests that simply checking the box as to the presence or absence of a policy or job description isn’t enough in measuring the effectiveness of a compliance program. Interviews with key executives and staff should be conducted to gauge their levels of awareness and recognition of the difference between a “paper” and an effective compliance program. While it may be wise to repeat some elements of the assessment each year, others should be chosen based on perceived current risks and deficiencies. In other words, compliance officers should carefully select those Resource Guide metrics that are most pertinent to the present needs of their particular compliance program and organization, and develop a practical game plan as to how to start to measure effectiveness across these metrics.

Part Three: The Impact of the Focus on Effectiveness and Recommendations for Providers

For decades, the federal government has encouraged health care organizations to develop effective compliance plans. In addition to helping reduce the likelihood of fraud, waste, or abuse of federal funds, government authorities touted such programs as a mitigating factor in investigations and as an opportunity to receive more favorable settlements in the event of a government investigation.

Despite the promising benefits of compliance programs and their critical importance to the provider organizations they protect, determining whether compliance programs were effective at meeting their intended goals was, in the past, a highly subjective endeavor. This is no longer the case following publication of the Resource Guide. The Resource Guide goes a long way towards suggesting how the OIG, the DOJ, and other government enforcement authorities may make that determination. As a result, health

³⁷ Resource Guide at 3.

³⁸ *Id.* at 16.

care providers should expect that government investigators will assess not only how the providers' compliance programs appear on paper, but also how the programs actually measure up against effectiveness metrics, like those set forth in the Resource Guide.

To this end, providers are encouraged to use all tools at their disposal to ensure that their compliance programs are, and, in the event of an investigation, will be perceived as, effective. By conducting regular (the OIG suggested yearly as early as the Hospital Supplemental CPG)³⁹ self-assessments and making any necessary enhancements to their compliance programs, organizations can greatly increase their opportunities to prevent compliance violations from occurring, catch those that do occur early, and receive beneficial consideration in the event of federal investigations of compliance issues that escalate outside of the organizations. These steps could significantly reduce the cost of any potential compliance problems, including potential mitigation against the imposition of costly, Corporate Integrity Agreements as part of any federal False Claims Act cases or other settlements with the federal government. In the authors' experience, providers that are able to demonstrate the reasonable steps they took through their own compliance program functions to reduce the risk of fraud, waste, and abuse are much better positioned when self-disclosing or defending against alleged misconduct. Thus, these recent guidance documents should inform compliance program effectiveness reviews going forward and providers should take care to appropriately document each step of that review process to preserve a record of their efforts.

Along these same lines, it is important to take note that the Resource Guide,⁴⁰ the 2017 FAQ,⁴¹ and the Sentencing Guidelines⁴² all encourage providers to engage outside expertise, as necessary, to assist in compliance program activities. Qualified attorneys, consultants, and other compliance professionals may be equipped to help providers in performing periodic effectiveness reviews. Indeed, it is more important now than ever for providers to make sure that their compliance programs are consistent with current

³⁹ Hospital Supplemental CPG, 70 Fed. Reg. at 4874.

⁴⁰ Resource Guide at 5, 13, 36.

⁴¹ 2017 FAQ at 2.

⁴² U.S. Sentencing Guidelines, Ch. 8, §§ B2.1(b)(5), (c) (2015).

industry standards.⁴³ Similarly, the Resource Guide recognizes that significant compliance concerns may be best addressed with the assistance of external counsel or other consultants.⁴⁴ Outside legal experts can help organizations understand the legal implications of the events being investigated, provide pertinent ongoing education to the governing board and management, assist in the remediation efforts including any self-reporting that may be necessary, and otherwise help organizations see these matters through to closure.⁴⁵

For providers contemplating their next compliance program effectiveness review, some of the following factors should be considered:

1. The compliance officer and organization's leaders should discuss and implement a self-assessment process for the compliance program as soon as is practicable;
2. This review process should be conducted at least annually, and should contribute to meaningful enhancements, as may be necessary, in the structure and responsibilities of the compliance program;
3. Each effectiveness self-assessment should be conducted in light of the metrics set forth in the Resource Guide, and all steps, findings, recommendations, and actions taken as a result of the effectiveness review should be appropriately documented. When determining which components of the Resource Guide to incorporate into their self-assessments each year, providers should take a practical approach and try to focus on known organizational risk areas and also any perceived compliance program gaps that have the greatest need for updating or enhancements;
4. Providers also should consider whether competent consultants or attorneys should be involved in performing these reviews to assist in applying the Resource Guide criteria to the particular compliance programs in question or to otherwise conduct more independent effectiveness reviews than may have been done in the past. In the event providers have reason to doubt the effectiveness of

⁴³ Resource Guide at 5, 13.

⁴⁴ *Id.* at 45.

⁴⁵ *Id.* at 49.

their compliance programs or have not yet implemented one, engagement of external expertise becomes an even more critical consideration;

5. As part of these ongoing effectiveness considerations, providers also should consider whether it is the right time to retain outside expertise to provide education and training to the governing board, management, the medical staff, or other constituencies on important compliance risks and strategies affecting their organizations. Keeping organizational stakeholders informed and engaged in this manner, and building a record of these kinds of meaningful compliance education activities, will help providers build impressive effectiveness records if later subject to government review;
6. Finally, in the event providers detect high-risk issues through the review or operations of their own compliance program, providers should make sure they have competent legal advisors to help guide them to a satisfactory and complete resolution of those issues. The stakes are too high in the health care enforcement arena for organizations to take on these challenges without access to the requisite external expertise.

Conclusion

The publication of the Resource Guide is a significant development in health care compliance. Providers now have numerous objective criteria at their disposal to use when reviewing in a more comprehensive manner the effectiveness of their compliance programs. Of course, the enforcement agencies now, too, have the same set of criteria to consider when investigating providers and deciding whether such providers should receive more favorable settlements or cooperation credit as a result of maintaining an effective compliance function. The authors therefore suggest that the time is now for providers across the health care industry to take the Resource Guide to heart, conduct their own self-assessments, and invest in their compliance programs as the best resource possible in trying to avoid the much bigger and more serious problems that typically occur when internal compliance functions break down and lose their effectiveness. In this regard, the Resource Guide could be viewed as a new opportunity

to promote effectiveness and we encourage providers to rely on it in a practical manner to enhance the success of their own compliance programs.

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