

Standards and Procedures: Codes of Conduct

Updated by Katherine A. Kuchan and Cara M. Tolliver

¶ 70,000 Introduction

* The recent publication from the United States Department of Justice, *Evaluation of Corporate Compliance Programs* (“DOJ Guidance”), reinforces the importance of a well-designed compliance program.¹ As a threshold matter, the government is charged with examining compliance program documents, including the code of conduct and compliance program policies and procedures. These documents form the basis of a well-designed compliance program and provide insight into the organization’s culture of compliance. It is appropriate that the first of the “seven essential elements” of an effective compliance program as identified in the United States Sentencing Guidelines is the establishment of compliance standards and procedures. This first element is the proverbial “first among equals” in that it directs the other elements toward the communication, monitoring, and enforcement of the enunciated standards and procedures.

As compliance represents and promotes an ethical and lawful way of doing business, a well-designed compliance program demonstrates an organization’s commitment to compliance with relevant federal and state laws and regulations. Commitment to compliance is intended to become part of the everyday life of the organization, emanating from the highest levels of governance and management and cascading throughout the organization to reflect a corporate culture of compliance that promotes integrity and ethical behavior.

As the most fundamental statement of the organization’s values and standards, a code of conduct will become the most public of the organization’s compliance statements and the minimum standards by which the effectiveness of its compliance plan (and to some extent the organization’s liability) will be judged. Failure to have standards and procedures of sufficient breadth, depth, and clarity and that are

meaningfully communicated to appropriate audiences may seriously jeopardize a compliance program no matter how well it is otherwise implemented. In order to create a process by which an organization can establish and maintain appropriate standards and procedures, it is necessary to understand and effectively operationalize each component of this essential element which addresses compliance standards and procedures.

¶ 70,005 Federal Guidance

The organization must have established compliance standards and procedures that are “reasonably capable of reducing the likelihood of criminal conduct” by employees and other agents.² Deceptively simplistic and concise in its terms, this passage from the federal Sentencing Guidelines Manual is directive only, providing health care organizations with very little guidance as to its full ambit or implementation. This single sentence makes reference to the following components.

1. *The substance of compliance.* To enforce standards of conduct, the organization must develop public statements of the organization’s compliance standards based on the legal obligations that the organization seeks to address in its compliance program.
2. *The various audiences to whom these substantive standards will apply.* Those subject to these compliance standards extend beyond employees of the organization to include its “agents.” In this context, *agent* includes not only a director, officer, or employee but also an independent contractor or “other person” authorized to act on behalf of the organization.³
3. *The process of compliance—both the process by which substantive compliance is achieved and the process by which an organization must respond to suspected compliance failures.* Procedures in this

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¹ U.S. Dep’t of Just., Crim. Div., *Evaluation of Corporate Compliance Programs* (Upd. June 2020), available at <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

² See U.S. Sentencing Comm’n, 2018 Guidelines Manual § 8B2.1 cmt. n.1.

³ U.S. Sentencing Comm’n, 2018 Guidelines Manual § 8A1.2 cmt. n.3(D).

context encompass not only procedures designed to assist employees and agents in avoiding violations of law but also procedures that will be required to: (1) monitor compliance with the standards, (2) enforce compliance standards within the organization and (3) respond both internally and externally to suspected or reported compliance failures.

4. *A qualitative criterion by which the standards and procedures will, in part, be judged.* Lastly, the above passage from the federal Sentencing Guidelines Manual contains a qualitative criterion, namely that the standards and procedures be designed and implemented in a manner that is reasonably capable of reducing the prospect of criminal misconduct.

Beyond the stated element itself, there are references to compliance standards and procedures in four of the remaining six compliance plan elements that provide further guidance as to the content and form of the standards to be developed. Standards and procedures must be capable of being effectively communicated to all employees and agents, capable of compliance evaluation through monitoring and auditing and subject to enforcement.⁴ Although the federal Sentencing Guidelines suggest that the size of the organization will be a factor in evaluating the requisite degree of formality of a compliance program, (often interpreted by smaller organizations that written policies defining standards and procedures may not be required),⁵ recent DOJ Guidance strongly suggests otherwise. DOJ Guidance indicates that prosecutors will make reasonable, individualized determinations in each case. These determinations suggest that compliance programs should achieve an appropriate level of evolution and growth over time.⁶ Organizations no longer receive

“brownie points” for simply having a compliance program. Instead, regardless of size, an organization’s compliance program must be in a position to respond “Yes” to the following three fundamental questions:

1. “Is the corporation’s compliance program well-designed?”
2. “Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?”
3. “Does the corporations compliance program work” in practice?”

In order to adequately respond to these questions, it is imperative that organizations contemporaneously document their internal controls and compliance efforts, including documentation of compliance policies and procedures. Irrespective of the organization’s size or type, written standards and policies provide credibility, consistency in interpretation and application and importantly, evidence of the organization’s culture of compliance in its day-to-day operations.

For a health care provider in search of authoritative guidance on the application of the standards and procedures element as well as other compliance plan elements, a primary source of information is the Office of Inspector General’s (“OIG’s”) various Compliance Program Guidances (“CPGs”). Since 1997, the OIG has published and updated 15 CPGs covering 12 different provider types.⁸ These statements provide guidance on the values and fundamental principles of compliance programs for each provider type and include specific elements that OIG expects to be addressed in the development and implementation of an effective compliance program. Specifi-

⁴ See U.S. Sentencing Comm’n, 2018 Guidelines Manual §8B2.1(b)(4)-(7), (c).

⁵ U.S. Sentencing Comm’n, 2018 Guidelines Manual §8B2.1 cmt. n.2(C).

⁶ See U.S. Dep’t of Just., Crim. Div., *Evaluation of Corporate Compliance Programs* (Upd. June 2020), available at <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

⁷ U.S. Dep’t of Just., Justice Manual, 9.28.800 Corporate Compliance Programs.

⁸ The first OIG Compliance Program Guidance was released for hospitals in 1997 with a supplement in 2005. Subsequently,

similar guidances have been issued for home health agencies (1998), clinical laboratories (1998), and third-party medical billing companies (1998), durable medical equipment companies (1999), hospices (1999), Medicare Advantage organizations (formerly Medicare+Choice) (1999), nursing facilities (2000 with a 2008 supplement), individual and small group physician practices (2000), ambulance supplies (2003), pharmaceutical manufacturers (2003), and recipients of Public Health Service (PHS) research awards (2005 draft guidance). Each CPG is available at <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>.

cally, OIG has stated the following in guidance on compliance standards:

Every compliance program should require the development and distribution of written compliance policies that identify specific areas of risk to the [health care provider]. These policies should be developed under the direction and supervision of the chief compliance officer and compliance committee, and, at a minimum, should be provided to all individuals who are affected by a particular policy or issue, including [the provider's], agents and independent contractors.⁹

With respect to standards of conduct, OIG advises:

[Providers] should develop standards of conduct for all affected employees that include a clearly delineated commitment to compliance by the [provider's] senior management and its divisions, including affiliated providers operating under the [provider's] control, [provider's] physicians and other healthcare professionals . . . Standards should articulate the [provider's] commitment to comply with all federal and state standards with an emphasis on preventing fraud and abuse. They should state the organization's mission, goals and ethical requirements of compliance and reflect a carefully crafted, clear expression of expectations for all [provider's] governing body members, officers, managers, employees, physicians, and where appropriate contractors and other agents. Standards should be distributed to, and comprehensible by, all employees (e.g., translated into other languages and written at appropriate reading levels where appropriate). Further, to assist in ensuring that employees continuously meet the expected high standards set forth in the code of conduct, any employee handbook delineated or expanding upon these standards of conduct should be regularly updated as applicable statutes, regulations and federal healthcare program requirement are modified.¹⁰

While the Hospital CPG generally is considered the "gold standard" model for compliance programs, the OIG provides other provider types, including physician practices, with more flexibility, since limited resources may prevent the establishment of a full-scale compliance program. For example, in its physician practices guidance, the OIG does not list a code of conduct as one of the seven basic elements of an effective compliance program. However, given the OIG's and DOJ's emphasis on organizational investment and improvements in compliance, physician practices would be well advised to develop and implement a code of conduct. A code of conduct is relevant to every health care provider and organization, regardless of type or size because it publicizes the organization's ethical norms and is a foundational element of any compliance program. At minimum, smaller practices should consider developing an abbreviated code of conduct as a relatively easy-to-develop tool for defining the organization's culture of compliance and promoting the organization's commitment to compliance.

The following excerpts provide important additional information on the context and content of compliance standards and policies and summarize the other compliance plan elements as they impact this principal element.

- OIG believes that it is incumbent upon an organization's corporate officers and managers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate ethical and lawful conduct.
- OIG is looking for both broad statements of business and ethics principles consistent with the organization's mission and goals. Standards should state the organization's mission, goals and ethical requirements of compliance and reflect a carefully crafted, clear expression of expectations for all hospital governing body members, officers, managers, employees, physicians and, where appropriate, contractors and other agents.
- The OIG recognizes that not all standards, policies and procedures need to be communicated

⁹ See e.g. Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8989 (Feb. 23, 1998).

¹⁰ See e.g. Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8989-90 (Feb. 23, 1998).

to all employees. However, the OIG believes that the bulk of standards relating to compliance with fraud and abuse laws and other ethics principals should be addressed and integrated into affected employees' training. The organization must appropriately decide which additional educational programs should be administered to certain types or levels of employees based on job functions and areas of responsibility.

- OIG recognizes that implementation of a compliance program may not entirely eliminate improper or unethical conduct from the organization's operations; however, an effective compliance program demonstrates the organization's good faith effort to comply with applicable statutes, regulations and other federal health care program requirements, and may significantly reduce the risk of unlawful conduct.
- OIG believes that compliance programs are not static and must evolve and change over time to meet the needs of the organization and address operational risks.

¶ 70,010 Implications for Written Policies

The previous discussion suggests that there are a number of audiences for whom the organization's written standards and procedures will be significant. These audiences generally can be classified as internal and external.

Internal audiences include:

- governing board and management;
- employees; and
- patients.

External audiences include:

- vendors and other third parties with whom the organization conducts business;
- members of the community;
- accrediting agencies;
- the regulatory and legal community, including agency officials, prosecutors and judges; and
- shareholders and other prospective investors.

Every effective compliance program necessarily begins with a formal commitment to compliance by high-level leaders, including the hospital's governing body and senior management. The OIG

strongly encourages involvement by the organization's governing body, Chief Executive Officer ("CEO"), chief operating officer, general counsel, chief financial officer and appropriate medical personnel in the development of standards of conduct. This high-level involvement helps to facilitate the communication of a strong and explicit statement of compliance goals and standards. These goals and standards are most often communicated in the organization's code of conduct which becomes the threshold-level document embodying the organization's culture of compliance. The code of conduct reflects the public character of the organization and should unequivocally state the organization's mission, goals and ethical requirements of compliance. The code of conduct should include a carefully crafted, clear expression of expectations for all hospital governing body members, officers, managers, employees, physicians and, where appropriate, contractors and other agents. The code of conduct should be distributed to all employees in a comprehensible manner (e.g., translated into other languages and written at appropriate reading levels, where appropriate).

Further, every compliance program should require the development and distribution of written compliance policies that identify specific areas of risk to the organization. These policies should be developed under the direction and supervision of the chief compliance officer and compliance committee, and at a minimum, should be provided to all individuals who are affected by the particular policy at issue, including the hospital's agents and independent contractors. To the employee, compliance policies may become not only standards and procedures governing their conduct, but implicitly or explicitly, terms of employment, since effective compliance plans include mechanisms for enforcement, including employee discipline.

An organization's compliance policies reflect the standards by which the organization will be judged. For prospective patients, the existence of clear, well-publicized and well-written policies provides a sense of confidence and peace-of-mind as to the standards and values by which they will be treated clinically and administratively. To the organization's business community, the existence of written compliance standards and policies indicates that

the organization is a good corporate citizen who can be confidently relied upon in business transactions. Importantly, these same standards will come under critical scrutiny by regulatory agencies when misconduct is suspected or identified.

In sum, the standards, policies and procedures that the organization sets forth will form the floor by which the organization's compliance conduct is judged. Such standards and policies can be the shield by which the organization defends itself or the sword upon which the organization falls. To prevent the latter catastrophe, organizations should ensure that their compliance programs are positioned to detect and respond to potential compliance concerns or misconduct no matter where or at what level within the organization the concern arises. An effective compliance program begins with a solid foundation and investment in compliance.

**¶70,015 Written Policies and Procedures:
Introduction**

At first glance, drafting a code of conduct along with policies and procedures “reasonably capable of reducing the likelihood of criminal conduct” is a daunting task. While there is no required form in which written policies and procedures must be set forth, many organizations use a general code of conduct supplemented by specific compliance policies and procedures. The code of conduct is frequently designed to generalize broad standards of conduct that apply to all employees. Additionally, the organization may include generalized compliance policies that outline the organization's commitment to comply with, for example, Medicare and Medicaid program requirements for accurate claim submission. Flowing from and consistent with these codes of conduct are more specific policies that describe the individual operating units' commitment to the compliance process in a manner that reflects the operating units' activities. These risk-specific policies should be designed to include a recognition of the organization's obligations under specific sets of laws (e.g., False Claims Act, Stark Law, Anti-Kickback Statute, Civil Monetary Penalties Law, etc.), developed in detail so as to meaningfully inform employees of what is required of them in undertaking their job responsibilities. These policies must contain statements that clearly identify the standards to

which the employees will be held and the types of conduct that a policy is designed to eliminate. Procedures appropriate to implement these policies are important since they will inform employees as to *how* to act in conformance with the organization's legal obligations with respect to a particular activity.

A separate category of policies and procedures is designed to implement the other elements of an effective compliance plan and, in particular, to guide responses to suspected compliance failures or misconduct. These policies and procedures do not address compliance with substantive legal obligations or prohibitions but rather address the compliance process. Some examples include the following matters:

1. Board of Directors (“Board”) approvals, oversight and responsibility of the compliance committee and senior leaders;
2. communicating standards and procedures effectively;
3. monitoring and auditing systems designed to detect compliance failures;
4. enforcing standards consistently; and
5. responding appropriately to offenses and taking steps to prevent their recurrence.

¶70,020 Form of Written Policies

There is no single form or “one-size-fits-all” approach for written compliance policies and procedures. Instead, providers should take an approach that works best for their organization, keeping in mind the following OIG guidance.

- Regularly review and update policies and procedures with department managers and the compliance committee.
- Assess whether each policy and procedure is tailored to the intended audiences and their associated job functions.
- Ensure that drafting is clear.
- Include “real-life” examples.

Additionally, in “real life” there is benefit to simplicity. Accordingly, when drafting policies and procedures, providers should also keep in mind that introducing too much complexity can undermine the goal to create clear expressions of expectations that

meaningfully inform the organization's various audiences.

Finally, standards, policies and procedures should also:

1. represent the mission, values and ethical standards of the organization;
2. address the laws that are applicable to the operations of the organization and its components both as a business generally and as a health care provider; and
3. be effectively adapted for the particular organization, given its structure, culture and management style.

Applying these principals to the code of conduct, we must first recall that the code of conduct reflects, both internally and externally, the organization's commitment to corporate compliance and its compliance approach. If the code of conduct is poorly drafted and focused merely on liability exposures as mandated by the government, it will not resonate to reflect the organization's expectation that all individuals adhere to the values and commitments of the organization in addition to all applicable laws, regulations and rules.

The code of conduct should address broader-level commitments, such as practicing with integrity and due respect for all individuals. It is also an opportunity to convey broader-level commitments that reflect the organization's focus on regulatory compliance, ethics, patient-centered care, integrity and respect for those in the community. It is the single most important description of the organization's business and compliance framework and a signal to employees, patients, business partners and the community that "doing the right thing" is welcomed and supported—regardless of the outcome. The code of conduct should convey to individuals a sense of safety for bringing compliance concerns to the organization.

It is critical for a code of conduct to reflect the organization's support for compliance starting with the very top of the organization. This tone is most often set by an organization's Board, CEO and other senior leaders, including the compliance officer. The "tone from the top" should evidence the organization's culture of compliance. The federal Sentencing

Guidelines have emphasized the importance of tone from the top in an organization's written code. Codes of conduct that implement a convincing show of support and tone from the top communicate that management takes adherence to the code seriously and that the rest of the workforce should accordingly follow suit.

In establishing a credible tone from the top, a variety of formats may be utilized. Generally, however, common formats include communication from the Board or CEO introducing to all employees the organization's code of conduct. When drafting an executive introduction, key considerations include the following:

- Is the statement adapted to the company culture and vocabulary?
- Is the statement written in the CEO's voice and style?
- Is the statement personalized and updated periodically so that it doesn't become stale?

Codes of conduct also must establish the methods for asking questions and reporting perceived or actual violations of the code, other company policies and law. Communicating an "open door" policy is no longer sufficient; employees must be given a range of reporting options. Codes will commonly include an anonymous reporting hotline, an online reporting mechanism (either website or email) and a list of the names and departments where employees can seek assistance in reporting.

Because organizations often have a difficult time convincing their employees that they will not be subject to retaliation for making a report or participating in an investigation, best practices dictate that a code should discuss non-retaliation early and often. In general, this means that the executive introduction includes a reference to the organization's commitment to non-retaliation, and that a clear statement of non-retaliation is included elsewhere in the code of conduct. Further, non-retaliation should also be the subject of its own policy.

Some organizations commence with a code of ethics statement followed by a code of conduct containing specific statements of the organization's standards and commitments in the conduct of its business affairs on specific topics. The scope of the

code of conduct will be influenced by the organization's size and provider type. Typically, the code of conduct includes, but is not limited to the following topics:

- purpose of the code of conduct;
- delivery of health care services;
- honest and ethical practices;
- non-retaliation;
- conflicts of interest;
- laws and regulations;
- exclusion;
- relationships with vendors, suppliers and contractors;
- gifts;
- documentation;
- billing and claims;
- privacy and confidentiality;
- solicitation;
- political activities, including lobbying and contributions;
- tax-exempt or governmental status;
- environmental concerns;
- use of alcohol and illegal drugs;
- workplace safety, security and health;
- equal employment opportunity; and
- protecting company assets.

In essence, the code of conduct outlines the organization's values and provides employees, including physicians, with direction on how to conduct themselves in executing their job responsibilities generally and how to proceed if they have a compliance concern. The code is followed by specific policies directed to operational risks.

¶ 70,025 Sources and Process of Drafting Written Policies

The process by which codes of conduct, policies and procedures are drafted is critical to their effective implementation and use by the intended audiences. Traditionally, the process is coordinated by the compliance officer or the compliance committee

and should follow an established policy as outlined in the organization's policy for policy development. The individuals who are responsible for policy development must also have expertise in the area under policy development. As one possible strategy for policy development, organizations may wish to consider forming a policy subcommittee of the compliance committee. Membership on the policy subcommittee should be limited to just a few members while tapping into key management and operational personnel so as to provide fluid and flexible expertise based on the particular policy or policies under review. The goal of the policy subcommittee is to provide oversight, guidance, review and input on implementation and education.

New policies and procedures (and those requiring updates) should be carefully reviewed. Providers should also consider having individuals who will be subject to the policies review them. While this may seem like a cumbersome task at first, with the subcommittee's input and the involvement of certain key operational leaders, it should be easy to identify individuals for this level of review. Critical analysis can help point out unnecessary or ineffective policies relative to the risk or goal in mind. A policy or procedure that does not make sense to the target audience will not be used or followed and only becomes a potential liability to the organization. "Effective" compliance policies are those that are "carefully crafted, clear expressions of expectations" and are "comprehensible by all employees."¹¹ Organizations must anticipate the possibility that employees may be interviewed or become witnesses testifying in support of or against the effectiveness of the compliance plan. If policies are not understandable to target employees in a way that is meaningful to their day-to-day job responsibilities, it is better to know that before implementing the policy so that the policy can be further revised, rather than to discover a policy shortcoming after a compliance failure or misconduct occurs.

Although there are many commonalities in the topics included in the code of conduct and compliance policies and procedures, there are also topics that are tailored to each particular organization and

¹¹ See e.g. Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8989-90 (Feb. 23, 1998).

its operational risks. Health care organizations should consider reviewing the following sources to help identify additional topics for inclusion in compliance policies:

- the organization’s existing standards of conduct, policies and procedures (as written or as custom or practice);
- the results of the organization’s risk assessments, including legal and compliance audits;
- OIG’s CPGs and other government sources;
- industry practice; and
- the organization’s compliance experience.

The identification of policy context sources closely tracks to the identification of legal and other operational risks that must be addressed in written policies. Both begin with certain fundamental questions:

- What does this organization do as a business entity generally and as a health care provider specifically that is regulated or otherwise governed by law?
- What specific operations or functions in the organization are subject to such laws, and how, in the regular conduct of business affairs, is the organization at a risk of violating those laws?

Some risks are more apparent than others, and some have undoubtedly been addressed in policies existing within the organization. Existing policies should be inventoried and reviewed to determine appropriateness, adequacy and effectiveness, and may need to be modified and supplemented, as appropriate, consistent with current regulatory mandates. New policies should be cross-referenced to

existing administrative policies that may provide procedures applicable to policy implementation.

One excellent source of information for policy development is the results of risk assessments that evaluate current operational compliance with applicable laws and regulations and the severity of risk. Detailed policies and procedures should address the legal and regulatory risks relevant to the organization. One organization may require a policy to address a particular high-risk issue that another organization does not require because the issue was deemed low-risk. As the spectrum of risk varies from organization to organization, there is, once again, no one-size-fits-all approach for compliance policies and procedures.

The OIG’s CPGs also contain a compendium of identified operational risks that OIG expects a health care provider to address in written policies and procedures. At a minimum, these “official areas of OIG’s concern” should be considered.¹² The rationale for any decision to exclude one of these areas of concern from the substance of compliance policies should be recorded in the compliance committee’s documents. Similarly, fraud alerts and advisory opinions issued from time to time by OIG are a further source of topics to be considered for written policies and procedures as applicable to the organization.¹³

The effectiveness of compliance plans will be judged not only by acknowledgment of governmental pronouncements but also by the degree to which the plan takes cognizance of best practices within the provider’s industry segment. An increasing number of large organizations have placed their policies and procedures on the Internet to facilitate employee access to their most current policies and procedures,

¹² OIG believes that written policies and procedures should take into consideration the function for each department of the health care provider, with special emphasis on areas of concern that have been identified by OIG through its investigative and audit functions. In each Compliance Guidance, OIG identifies those areas. For example, in the Compliance Guidance for hospitals, OIG identifies areas of concern to include billing for services not rendered; providing medically unnecessary services; upcoding; the DRG creep; outpatient services rendered in connection with inpatient stays; teaching physicians and residence requirements for teaching hospitals; duplicate billing; false cost reports; unbundling; billing for discharge in lieu of transfer; patients’ freedom of choice; credit balances (failure to

refund); hospital incentives that violate the anti-kickback statute or similar federal or state statute regulations; joint ventures; financial arrangements between hospitals and hospital-based physicians; the Stark law on physician self-referral; knowing failure to provide covered services or necessary care to members of an health maintenance organization; and patient dumping. The Compliance Guidance applicable to the nature of the organization should be viewed to obtain a similar listing of OIG’s areas of special concern applicable to that provider. This should be supplemented by review of OIG Fraud Alerts, Advisory Opinions, and the current OIG Work Plan.

¹³ OIG Fraud Alerts and Advisory Opinions are available from OIG’s website.

while companies listed on major U.S. stock exchanges are required to make public their code.¹⁴ Compliance plans of similar organizations and materials from compliance trade associations and consultants (i.e., certain law firms, accounting firms and other consultants) provide sources, topics or suggested approaches to certain policies and procedural issues.

Last, among the topics presumably encompassed in a legal audit or risk assessment is the compliance history of the organization, including compliance failures and misconduct, refunds to fiscal intermediaries, self-disclosures and settlements with government agencies, to name a few.

¶ 70,030 Communication of Written Policies

No policy or procedure will be effective if it is not communicated and understood by those subject to it. Unsurprisingly, DOJ highlights accessibility and operational integration of policies and procedures as two key components of a well-designed compliance program.¹⁵ For example, DOJ asks organizations to consider:

- “How has the company communicated its policies and procedures to all employees and relevant third parties?”
- “Have the policies and procedures been published in a searchable format for easy reference?”
- “Have policies been rolled out in a way that ensures employees’ understanding of the policies?”
- “In what specific ways are compliance policies and procedures reinforced through the company’s internal control systems?”¹⁶

In addition, the following points should be considered for a healthy policy implementation process.

- Although all employees need to be aware of the generalized code of conduct, specific rules and policies relating to particular functions should be communicated only to those employees to whom those policies apply.

- Health care organizations have a diverse workforce, including diversity of backgrounds, languages and education levels, to name a few. Organizations must accommodate these differences.
- A central theme in compliance plan implementation is documentation of compliance efforts. Requiring employees to provide written acknowledgment of their receipt and comprehension of and agreement to abide by the codes of conduct and applicable policies and procedures is an important safeguard. The acknowledgment should at minimum (1) refer to the nature of the compliance documents received, (2) note that the documents were reviewed, explained or discussed and (3) acknowledge by signature and date (written or electronic) the recipient’s understanding of and agreement to abide by the terms outlined in the compliance documents.
- Accessibility of current policies and procedures is critical. The substance of policies and procedures can take many forms, and consultation with communication specialists is suggested. The goal is to keep the substance of policies fresh in the minds of employees rather than to have them become merely reference documents on a shelf or intranet site. For geographically dispersed organizations, use of a website is an efficient cost-effective means of keeping codes of conduct, policies and procedures readily accessible to employees. Compliance policies that are not accessed or used but remain “on the shelf” become potential liabilities to the organization.

¶ 70,035 Policy Maintenance

Change is constant. The industry itself changes; reimbursement rules change; regulations change; organizational structures change; and personnel change. Policies that are appropriate and effective today may be materially impacted by a change tomorrow. Compliance plans and policies that are out of date place the organization at risk. Accordingly, organizations must monitor various statutory and

¹⁴ Available on the NASDAQ’s and NYSE’s respective websites.

¹⁵ See U.S. Dep’t of Just., Crim. Div., *Evaluation of Corporate Compliance Programs* (Upd. June 2020), available at <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

¹⁶ *Id.*

regulatory guidance to ensure awareness of new developments or changes impacting the organization. Similarly, changes in an organization's operations require an assessment as to its impact on existing policies and procedures. Among the items on the organization's compliance committee agenda should be an assessment of the currency and adequacy of existing policies and procedures in light of government pronouncements, industry practices and the experience of the organization in implementing its compliance plan and responding to compliance failures.

¶70,040 Compliance Implementation Policies

Cutting across the substantive and preventative policies are those specifically designed to address the process of compliance in the implementation of the other six compliance program elements. These policies and procedures focus on employee and vendor screening, communication and reporting, compliance monitoring, investigations and responding to prospective compliance failures. Of note, the highest level of sensitivity and caution must be funnelled into the development of policies and procedures relating to compliance investigations and enforcement. In drafting such policies, a balance must be achieved among the following priorities:

- meeting government expectations of the compliance plan;
- evaluating and responding to the compliance failures;
- protecting the interests of the organization in so responding; and
- protecting the interests of individuals involved in the investigation and response process.

More than in any other area of compliance policy development, in this arena concerning compliance investigations and enforcement policies, counsel should be consulted. The drafter must have both deep and practical knowledge of the various courses that compliance investigations may take both internally and externally. This includes understanding when investigations should proceed under the attorney-client privilege. A policy addressing privileged investigations is a must. Policies and procedures surrounding investigations should provide adequate leeway so that judgments can be made

during the course of an investigation as to the nature and severity of the potential misconduct and the appropriate remedial measures. At the same time, it is essential that the policies and procedures be sufficiently directive to ensure that there is a final determination as to the nature, significance and ultimate disposition of the matter, either internally or in a process with an outside agency, if the facts so warrant. The policies should also clearly provide that investigation reports reach senior management and the governing body for their consideration of material compliance breaches, impacts to the organization and the adequacy of remedied measures—a process that is far too frequently left unaddressed in written compliance plans and everyday practice.

Concurrently, the policy drafter must also recognize issues that may arise internally during compliance investigations and anticipate them in compliance policies and procedures. These policies should provide senior leaders with the authority to establish and enforce disciplinary standards for both misconduct and employee failures to follow compliance policies. Policies should clearly provide notice to all employees that violations of law, codes of conduct and other compliance policies and procedures are matters subject to discipline. Necessary policies must also address confidentiality and protection of employment rights, including non-retaliation in connection with reports and investigations of potential or actual compliance failures and misconduct. These policies should be developed in consultation with legal and human resource professionals within the organization.

¶70,045 Assessing Effectiveness of Standards, Policies and Procedures

As critical as it is for an organization to develop and maintain a compliance program, it is just as critical that the organization assess the effectiveness of its program. Since there isn't a one-size-fits-all program, periodic effectiveness reviews are one way to assist organizations in objectively demonstrating how they proactively measured their compliance programs' effectiveness and improved it when necessary. OIG's 2017 Resource Guide which was developed in partnership with the Health Care Compliance Association is a valuable tool to assist organizations in measuring the effectiveness of

every aspect of their programs, including standards, policies and procedures.¹⁷ The Resource Guide provides extensive metrics that organizations can use either to review their programs comprehensively from top to bottom or to take a more targeted approach with assessment of only certain elements as based on the organization’s individual needs in a given year.

The Resource Guide outlines a total of 650 separate individual effectiveness measures across the seven elements. Sixty-two measures are directly related to standards, policies and procedures. The Resource Guide provides a list of best practices and then offers suggestions on “what to measure” and “how to measure.” The measures are further subdivided into various categories to address accountability, review and approval process, quality, assessment, code of conduct, updates and understanding, to list a few.¹⁸ The suggestions help organizations determine whether their compliance policies are accessible and accessed in practice by the relevant employees. They also help organizations evaluate whether policies are high-quality documents written in plain language and developed with the input of key stakeholders. Other suggestions get to the heart of why organizations should have policies and procedures in the first place—do the policies and procedures assist employees in doing their jobs effectively?¹⁹ Still other suggestions seek to under-

stand and identify potential gaps at the highest levels of the organization, “testing” Board and c-suite members on their knowledge and understanding of policies and the policy development, distribution and enforcement process.²⁰ As enforcement measures, one-on-one interviewing, observations and data collection are tools that will assist organizations in gathering information and completing either a self-assessment or a more formal compliance program review with the assistance of an experienced third-party reviewer. Importantly, effectiveness reviews provide organizations with a glimpse of how government enforcement agencies might view the effectiveness of their compliance programs. Organizations should use these suggestions as an opportunity to ensure that their compliance programs meet or exceed industry standards.

Written standards of conduct and compliance policies and procedures address both the substance and the process of compliance. They are the rules by which all employees in the organization must operate, and they establish the minimum standard by which the organization will be evaluated by its employees, the community and the government. Standards, policies and procedures should not only mitigate compliance risk but should also reflect the organization’s business ethics and commitment to compliance.

¹⁷ Office of Inspector General & Health Care Compliance Ass’n, *Measuring Compliance Program Effectiveness: A Resource Guide*, (Mar. 27, 2017), available at <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>.

¹⁸ *See id.* at pgs. 2-7.

¹⁹ *Id.* at pg. 4.

²⁰ *Id.* at pg. 7.