New Expectations for Compliance Programs

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I. Background
II. Review of Traditional Core Elements
  a. Designated Compliance Officer and Administration
  b. Written Standards of Conduct
  c. Comprehensive Training and Education
  d. Open Lines of Communication
  e. Internal Auditing and Monitoring
  f. Enforcement, Discipline, and Incentives
  g. Response and Remediation
III. New Framework
  a. Program Design
  b. Good Faith Implementation
  c. Effectiveness in Practice—Operation
  d. Common Inflection Points
IV. New or Expanded Expectations
  a. Management inadequacies and accountability
  b. Data Analytics
  c. Mergers, acquisitions, and transactions
  d. Third party risks and diligence
  e. Appropriate risk analysis
V. Practical Suggestions
VI. Ethical Concerns for Compliance Counsel
  a. Organization as a Client
  b. Scope of Representation
  c. Roles of a Lawyer
  d. Duties to Report
VII. Summary

Where? Where does the Healthcare Compliance path lead? Have you ever stopped to think how we got here? How did

we move from ethics to a relatively healthy reliance on the seven traditional elements of an effective compliance program, and where do we go from here? Will we have a compliance GPS system to help us navigate a more complex, technology-driven environment and ever-expanding corporate and regulatory borders? What ethical, legal, regulatory or business models will shape our program structure and methods? What rules, regulations, industry best practices and/or guidance will help inform the advice we give to our clients going forward?

To meet future challenges, healthcare compliance leaders will have to go beyond the traditional elements. Some compliance programs have narrowly focused on those elements.[1] This was a great foundation, but the industry has evolved from a fee-for-service model into a much more complex ecosystem, and compliance programs can develop gaps and vulnerabilities if they become complacent. They must recognize how regulations across different industries have woven into a complex matrix that encompasses healthcare. Going forward, as healthcare evolves and healthcare companies become multifaceted, healthcare compliance programs must look beyond their own, business-specific regulatory requirements. They will need to see the intricate regulatory connections among disparate industries and regulatory agencies and understand how rules, best practices and methods in banking, finance, and technology will impact healthcare.

No person is an island, nor can one person keep up with the dynamic legal and regulatory environment. To be successful, healthcare compliance practitioners must shift to a strategic approach and align with business partners if they are to be effective. Compliance leaders will need to see beyond the traditional elements to strategic solutions. Collaboration and transparency will be important. Compliance professionals will have to be consumers of data and technology. Technology and artificial intelligence will enable compliance to be nimbler, and more responsive.[2]

Luckily, the path forward is supported by a solid history. Yes, the traditional elements are old and seasoned, but they

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[1]Compliance Week, Wed, Sep. 30, 2020. Ask a CCO: What will compliance look like in 5 years?

[2]*Id*.

are proven and solid. After reviewing a background summary of recent developments, we review the foundational path and what is commonly understood to be incorporated within each of the seven core elements in the second section. The third section describes how the traditional elements have been incorporated into the framework of the newer DOJ Guidance. The fourth section describes new developments in the recent guidance that either create new expectations or materially expand upon former considerations. The fifth section provides some practical suggestions for implementing these new developments into existing healthcare compliance programs. The final section describes certain ethical considerations that commonly confront attorneys in the context of healthcare compliance.

I. Background

The U.S. Department of Health and Human Services Office of Inspector General ("OIG") began encouraging the private health community to diminish fraud and abuse through compliance programs more than two decades ago.[3] Although the government has continued to issue subsequent guidance documents with increasing complexity, it has generally recognized seven core elements that were understood to comprise an effective compliance program.[4]

The traditional seven core elements are found in the U.S. Sentencing Guidelines ("USSG") for organizations. Although the USSG provisions were originally established to standardize certain mitigating factors for organizations that had been convicted of criminal offenses, their elements were adopted into the early compliance guidance of the OIG and they continue to form the recognized foundational basis for health compliance programs. Thus, these provisions have become pertinent to transactional and civil practices.

The USSG comments elaborate on each element, providing more detailed expectations and establishing guidelines for

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[3] *See, e.g.*, 63 Fed. Reg. 8987 (Feb. 23, 1998).

[4] 42 C.F.R. § 422.503(b)(4)(vi)(A)–(G); *see also* U.S. Department of Health and Human Services, Office of Inspector General ("OIG"), Healthcare Fraud Prevention and Enforcement Action Team, *Provider Compliance Training: Health Care Compliance Program Tips*, ("Attachment A"). https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf

effective implementation.[5] Additionally, the OIG has published numerous guidance documents that specify how health care providers and other organizations should implement the traditional compliance program elements.[6] All of those expectations remain relevant.

During the past three years, however, several publications materially revised the focus of the seven core elements and created greater emphasis on certain components. The U.S. Department of Justice ("DOJ") Criminal Division Fraud Section revised its guidance regarding evaluation of corporate compliance programs in 2017,[7] and the revisions were updated and incorporated, in April 2019, into a Guidance Document for the Criminal Division which was revised again in June 2020 ("DOJ Guidance").[8]

Similarly, in March 2018, the DOJ announced that it would apply its Foreign Corrupt Practices Act ("FCPA") Corporate Enforcement Policy as nonbinding guidance in criminal cases outside the FCPA context. This announcement opened the possibility of more leniency and declination of prosecution in other enforcement matters.[9] In November 2018, the Benczkowski Memorandum cited similar factors to be considered in determining whether to include corporate in-

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[5]United States Federal Sentencing Guidelines ("USSG") § 8B2.1(a)(1), (b)(1) (2013).

[6]*See, e.g.,* 70 Federal Register ("Fed. Reg.") 4858–4876 (Jan. 31, 2005) (Supplemental Compliance Program Guidance for Hospitals); 63 Fed. Reg. 8989 (Feb. 23, 1998) (Compliance Program Guidance for Hospitals); HHS OIG, *Practical Guidance for Health Care Governing Boards on Compliance Oversight* (April 20, 2015).

[7]U.S. Department of Justice ("DOJ"), Criminal Division, Fraud Section, *Evaluation of Corporate Compliance Programs* (Feb. 8. 2017) (the "2017 Guidance").

[8]DOJ, Criminal Division, *Guidance Document: Evaluation of Corporate Compliance Programs* (June 2020) (the "DOJ Guidance"). https://www.justice.gov/criminal-fraud/page/file/937501/download

[9]The DOJ modified its FCPA corporate enforcement policy to create a presumption that the DOJ would decline criminal prosecution in the absence of aggravating factors if the company voluntarily self-disclosed its misconduct, fully cooperated, and timely and appropriately remediated. *See* DOJ, Justice Manual (the "JM") FCPA Corporate Enforcement Policy, § 9-47.120(1); *see also* Cronan, John and Benjamin Singer, American Bar Association National Institute on White Collar Crime, San Diego, California, March 1, 2018.

tegrity monitoring requirements into deferred prosecution agreements, non-prosecution agreements, or plea agreements.[10] In May 2019, the DOJ revised its Justice Manual commercial litigation guidelines for considering whether cooperation credit should be afforded to False Claim Act litigants that have voluntarily self-disclosed misconduct and employed effective remedial measures.[11] The Justice Manual was further revised, in July 2019, to update the guidelines for corporate compliance programs,[12] and in November 2019 to codify the FCPA enforcement policy.[13]

While these publications may be industry-agnostic, they have a significant effect on health industry enforcement. The Federal Health Care Fraud and Abuse Control Program is comprised of the DOJ, its Civil and Criminal Divisions and Federal Bureau of Investigation, and the OIG and Centers for Medicare & Medicaid Services within the U.S. Department of Health and Human Services. Collectively, the Federal Health Care Fraud and Abuse Control Program was responsible for recovering $3.6 billion through health care enforcement initiatives during federal Fiscal Year 2019.[14]

Taken together, these publications treat the structure, implementation, and practices of a compliance program more cohesively and demonstrate a swift movement toward adopting consistent enforcement and leniency policies. The revisions have woven new substantive expectations together with the traditional seven elements into a more complex analysis that evaluates not only the written components of a compliance program, but also determines whether the

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[10]DOJ, Brian A. Benczkowski, Assistant Attorney General, *Memorandum: Selection of Monitors in Criminal Division Matters* (Oct. 11, 2018) (the "Benczkowski Memo"). https://www.justice.gov/opa/speech/file/1100531/download

[11]DOJ, Justice Manual, *Commercial Litigation*, § 4.4.112 (May 2019). https://www.justice.gov/jm/jm-4-4000-commercial-litigation

[12]DOJ, Justice Manual (the "JM"), *Principles of Federal Prosecution of Business Organizations*, § 9-28.800 (July 2019). https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations

[13]DOJ, Justice Manual, *FCPA Corporate Enforcement Policy*, § 9-47.120 (Nov. 2019).

[14]U.S. Department of Health and Human Services and DOJ, *Health Care Fraud and Abuse Control Program: Annual Report for Fiscal Year 2019*, p. 8 (June 2020).

program has been implemented effectively in actual practice. It has become clear that the traditional "seven elements" understanding of a compliance program may no longer be sufficient to establish the ongoing effectiveness of an organization's compliance program.

At the same time, there has been a parallel reduction of deference to earlier subregulatory guidance. In 2018, the Brand Memorandum precluded DOJ litigators from using noncompliance with such guidance documents as a basis for proving statutory or regulatory violations in civil enforcement cases.[15] The Justice Manual formally implemented and superseded the Brand Memorandum later that year by adopting a new chapter that incorporated similar terms.[16] The Supreme Court's *Allina* opinion generally prohibits the government from changing any substantive legal standard relating to Medicare benefits, payment, or eligibility without adopting formal rules.[17] The subsequent CMS Cleary Memorandum clarified that if subregulatory publications are not closely tied to the enabling statutory or regulatory standards, then the government generally cannot use violations of that guidance to prove legal or regulatory violations.[18]

Some legal scholars contend that the overall concept of deference to agency interpretation is eroding. Defense practitioners may challenge a court's deference to agency interpretations to counteract overaggressive enforcement efforts, and such challenges could be supported by recent jurisprudence. While these legal developments continue to unfold, it is critical to remember that subregulatory guidance retains several legitimate purposes. For example, the Justice Manual expressly provides that such guidance documents may be used to prove scienter, notice, or knowledge of the law, or to establish professional, industry, or technical

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[15]DOJ, Brand, Rachel, Associate Attorney General, "Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases," p. 2 (Jan. 25, 2018).

[16]JM §§ 1-20.100 0 1.20.205.

[17]*See* Azar v. Allina Health Services, 139 S.Ct. 1804, 587 U.S. __ (2019).

[18]*See* HHS, Cleary, Kelly M., Deputy General Counsel and CME Chief Legal Officer, "Impact of *Allina* on Medicare Payment Rules," p. 2 (Oct. 31, 2019).

standards and processes.[19] Moreover, the U.S. Sentencing Guidelines expressly authorize the consideration of "applicable industry practice" as well as other factors in evaluating the effectiveness of a compliance program.[20] As such, the prudent compliance practitioner will continue to assist organizations in developing their compliance programs in accordance with applicable guidance.

II. Review of Traditional Core Elements

The purpose of this review is two-fold. First, it illustrates in detail just how much the scope of each element has expanded over time to include a vast array of corollaries and subcomponents. Second, it may be used as reference material, particularly for attorneys whose practices may not focus on compliance program assessment. This section reflects an attempt to review the primary authoritative resources published during the past two decades and consolidate their common material provisions into a single summary. If an expectation is articulated in this review, it has been published repeatedly as a standard is widely accepted within the industry as an essential component of that element.

The original seven core elements of an effective compliance program have evolved over time to incorporate more complex requirements and subcomponents.[21] For example, representatives from the OIG and the Health Care Compliance Association ("HCCA") conducted a roundtable meeting on compliance effectiveness in 2017, the result of which was the publication, *Measuring Compliance Program Effectiveness: A Resource Guide* (the "Joint Resource Guide").[22]

The purpose of the Joint Resource Guide was to compile the suggestions of industry leaders into a single reference containing as many ideas as possible about compliance metrics. The participants recommend that health industry organizations review the suggestions and choose which

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[19]JM §§ 1-20.201–1-20.205.

[20]FSG § 8B2.1, Comment 2(A), (B).

[21]*See* USSG §§ 8A1.2, 8B2.1 and Comments.

[22]HCCA and OIG, "Measuring Compliance Program Effectiveness: A Resource Guide," (Mar. 27, 2017). A thorough exploration of the resource guide is beyond the scope of this chapter.

metrics are most applicable to their operations. The Joint Resource Guide subdivides the seven traditional elements into one hundred thirteen (113) sub-elements, and those are further clarified into four hundred one (401) more granular components. This is what happens when advanced practitioners and policy wonks sit down for a roundtable discussion. The lesson is that the traditional elements cannot be read at face value. Each element infers a multitude of expectations.

The complexity of thinking about compliance, the substantive variety among compliance guidance sources, and evolving expectations can make it difficult to set accurate benchmarks. In the health industry, however, the most applicable and consistent compliance program guidance has been issued by the OIG. This section defines the traditional seven elements in accordance with the OIG's published compliance resources, including its joint publications with the HCCA and American Health Lawyers' Association ("AHLA").

We describe at a high level those attributes of each core element that are generally expected among health systems, larger health facilities and other large organizations.[23] With respect to smaller organizations, the objectives of these core elements may be achieved through less extensive efforts and by leveraging the expertise of other professionals.

a. Designated Compliance Officer and Administration

The first element is generally understood to be a designated compliance officer and appropriate compliance program administration. The Joint Resource Guide identifies twenty-four (24) sub-elements, and those are subdivided into sixty-eight (68) more granular factors that are consolidated and summarized more generally here. Taken together with the

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[23] *See, e.g.,* Health Care Compliance Association ("HCCA") and OIG, "Measuring Compliance Program Effectiveness: A Resource Guide," (Mar. 27, 2017); OIG, "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse," (Nov. 5, 2010); "OIG Supplemental Compliance Program Guidance for Nursing Facilities," 73 Fed. Reg. 56832, 56848 (Sept. 30, 2008); "OIG Supplemental Compliance Program Guidance for Hospitals," 70 Fed. Reg. 4858, 4874–4876 (Jan. 31, 2005); "Building a Partnership for Effective Compliance: A Report on the HCCA-OIG Physician's Roundtable," (Jul. 24, 2000); "OIG Compliance Program Guidance for Nursing Facilities," 65 Fed. Reg. 14289, 14291–14305 (Mar. 16, 2000).

U.S. Sentencing Guidelines and other health industry guidance, this core element is commonly understood to encompass the organizational structure of the compliance program, its budget and resources, and its reporting lines and obligations.

The primary administrative requirement is the designation of a qualified Chief Compliance Officer ("CCO") or equivalent senior executive compliance position that is responsible for development and administration of the compliance program. The CCO should be included as a key stakeholder in the strategic initiatives of the organization. An organization should establish the compliance program and its authority through documented Board Resolutions, a written compliance plan, policies, and other appropriate documentation.

Although the CCO directs compliance efforts, operational managers bear the ultimate responsibility and accountability for compliance. To that end, organizations should be able to demonstrate that they have conducted reasonable background and exclusion screening of all substantial authority personnel and contractors to ensure that they have not been excluded or engaged in illegal activities or other misconduct. This function is so important that the Joint Guidance described it as a standalone element.[24] Moreover, the U.S. Sentencing Guidelines discuss background checks at length and provide that participation or willful ignorance of misconduct by high-level personnel creates a presumption that the program was not effective.[25]

The compliance program must be vested with the autonomy, budget, and staffing resources to address the organization's identified risks on an ongoing basis. In larger organizations and given the appropriate circumstances, the CCO should have independent authority to retain outside counsel and be granted access to all relevant documents, systems, employees, and vendors.

The CCO should report to the Board or its compliance committee on annual or more frequent basis and should have direct access to the governing body as well as to key executives including the Chief Executive Officer. The governing body should receive education on compliance expectations

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[24]The background screening element is composed of eight (8) sub-elements and subdivided into forty (40) more granular factors.

[25]FSG § 8C2.5(B).

and remain engaged in reasonable oversight of the compliance program.

The CCO's relationship to the General Counsel is an area of specific interest to the OIG. The OIG has long noted that the CCO "should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner."[26] This has become a fairly standard condition of OIG Corporate Integrity Agreements ("CIA").[27]

Although the OIG has incorporated this condition into its CIAs, it has not become a hard rule, and many prominent health organizations do engage attorneys to act as CCOs.[28] Why? Mainly because lawyers make great CCOs. Many companies have lawyers serving as CCOs that are either lawyers by training or acting as a lawyer in that role. This holds true across many industries and has proven to be effective if not preferred. Further, state licensing boards require that all clients, including companies, have the right to choose their lawyers. This choice cannot be dictated by the government. Even though the in-house roles of CCO and legal counsel may diverge in responsibilities, most in-house counsel roles do require a wide range of business and legal responsibilities. Further, the roles tend to overlap more than conflict with each other because the General Counsel will be as concerned with compliance as the CCO. Ultimately, companies should be free to structure their leadership roles in a manner that best serves the appropriate interest of the entity.

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[26]OIG, Association of Healthcare Internal Auditors, AHLA, and HCCA, "Practical Guidance for Health Care Governing Boards on Compliance Oversight," p. 7 (2015); (citing OIG and AHLA, "An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors, p. 3 (2004); "Compliance Program Guidance for Hospitals," 63 Fed. Reg. 8987, 8997 (Feb. 23, 1998)).

[27]*See, e.g.,* Corporate Integrity Agreements in various regions between the OIG and Ra Medical Systems, Inc., California, (Dec. 28, 2020); Seery, Jesse, Integrated Labs, LLC, and Golden Management Team, LLC, Tennessee, (Dec. 20, 2020); Brooklyn Plaza Medical Center, New York ((July 14, 2020); Chronic Disease Fund, Inc, Texas (Oct. 24, 2019).

[28]Medicare has created a rule that prevents an ACO compliance officer from serving in a legal function.

b. Written Standards of Conduct

The USSG and the OIG both note the importance of written standards of conduct. OIG specifically notes that "[c]omprehensive compliance programs should include . . . the development and distribution of written standards of conduct, as well as written policies and procedures that promote the [organization's] commitment to compliance and that address specific areas of potential fraud . . ."[29] The USSG states, "to have an effective compliance and ethics program . . ., [an] organization shall establish standards and procedures to prevent and detect criminal conduct."[30]

The Joint Resource Guide identifies twenty-two (22) subelements arising out of written standards, and those are subdivided into sixty-two (62) more granular factors. This core element is commonly understood to incorporate Board Resolutions, the Code of Conduct, bylaws, policies and procedures, and management of those written standards.

Written standards should be reviewed on a periodic basis according to a written review and approval process. They should be updated as necessary to reflect developments in law or policy. They should be widely distributed throughout the organization, written in understandable language, and easily accessible. They should be maintained in accordance with a formal records retention policy.

Certain policies and procedures are generally understood to be indispensable in most health industry compliance programs. These include written standards for nonretaliation, conflict of interest, privacy and confidentiality, employee and management accountability, risk assessment, regulatory and health program policy requirements, fraud and abuse, credentialing and background screening, and interactions with third parties and other industry stakeholders.

c. Comprehensive Training and Education

With respect to training and education, the Joint Resource

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[29]Office of Inspector General. Publication of the OIG Compliance Program Guidance for Hospitals. 63 Fed. Reg. 35,8987 (Feb. 23, 1998). http://oig.hhs.gov/authorities/docs/cpghosp.pdf

[30]USSG § 8B2.1(b)(1)—EFFECTIVE COMPLIANCE AND ETHICS PROGRAM

Guide identifies thirteen (13) sub-elements, and those are subdivided into forty-nine (49) more granular factors. This element is commonly understood to include periodic compliance training and efforts to validate that such training was completed successfully.

Initial compliance training should be provided at employee orientation and annually thereafter. Some organizations will have affirmative contractual duties to provide training to and verify training of certain vendors and subcontractors prior to the inception of services.

Trainers should be qualified and experienced, and the materials should be appropriate to each person's responsibilities. An organization should maintain records of attendance and test scores or evaluations from its training sessions.

Training materials should be evaluated and updated periodically to incorporate program and legal developments. The substantive content should address fraud, abuse, and those risks that are most applicable to the organization.

d. Open Lines of Communication

The OIG identifies open communication as one of the traditional seven elements.[31] This core element is commonly understood to encompass publication of a hotline and other reporting mechanisms, anonymous reporting capabilities, and distribution of other materials to foster compliance.

An organization should maintain a written log of all hotline reports and track whether they were submitted anonymously. All incoming reports, whether through the hotline or other sources, should be tracked. The substance and resolution of such reports should be conveyed to the Board or governing body on a regular basis. The organization must publicize its anti-retaliation policy to protect those who report compliance concerns.

Compliance expectations should be communicated to all members of the governing body, staff, vendors, and contractors through job descriptions, performance appraisals, train-

[31]The Joint Resource Guide does not identify this as a separate element, but rather addresses open lines of communication within its discussions of education and training and internal reporting to monitors and auditors.

ing materials and policies. The CCO and his or her contact information should be distributed in newsletters, email blasts, and other compliance department communications.

e. Internal Auditing and Monitoring

The Joint Resource Guide identifies nineteen (19) sub-elements of the auditing and monitoring element, and those are subdivided into seventy-seven (77) more granular factors. This element is commonly understood to include risk assessments, routine monitoring or auditing across the organization, unannounced surveys and reviews, and analysis and reporting of the findings from those efforts.

Large organizations should develop a risk assessment tool and audit plan, both of which should be updated annually. These tools should prioritize the organization's most serious and most likely compliance risks. Auditing and monitoring efforts should include ongoing reviews of healthcare claims, billing, and supporting documentation, and should be designed to detect the root causes of improper billing. The results of auditing and monitoring efforts should be reported to the Board and officers on a routine basis. The compliance program itself should be reviewed for its effectiveness on an annual basis.

f. Enforcement, Discipline, and Incentives

The Joint Resource Guide identifies nine (9) sub-elements, and those are subdivided into thirty-four (34) more granular factors. The element of enforcement and discipline is commonly understood to include the publication of disciplinary standards and consistent enforcement, particularly as applied to revenue-generating employees and management. The organization should retain documentation to prove that misconduct has been disciplined appropriately. The organization should also assure that such disciplinary measures have been applied consistently across the organization, regardless of role, position or rank. Of course, it is always fair to account for unique facts and mitigating circumstances, such as prompt disclosure, severity and frequency of offense, honesty, and cooperation.

g. Response and Remediation

The Joint Resource Guide identifies eighteen (18) sub-

elements of response and remediation, and those are subdivided into seventy-one (71) more granular factors. This element is commonly understood to include proper investigation of reported matters, documentation of efforts and findings, analysis of root causes, and appropriate corrective action and remediation.

The organization should demonstrate an ability to investigate allegations of wrongdoing promptly, and to engage outside counsel, auditors, or other consultants when warranted. Investigations should be thorough, and the organization should retain all relevant documentation of its efforts and conclusions. The root causes for misconduct should be identified and addressed through repayment of any identified overpayments, disclosure to appropriate regulatory or law enforcement authorities, and the implementation of corrective action to prevent recurrences.

The U.S. Sentencing Guidelines provide that recurrence of similar misconduct will create doubt regarding the effectiveness of a compliance program.[32] If an organization failed to take reasonable steps to prevent or terminate an offense, it is considered to have condoned that offense.[33]

III. New Framework

The most comprehensive discussion of the government's new approach is set forth in the DOJ Criminal Division's *Guidance Document: Evaluation of Corporate Compliance Programs* (June 2020) (the "DOJ Guidance").[34] This document establishes that every evaluation of compliance program effectiveness should begin by asking three fundamental questions, each of which is addressed in turn:

1. Is the compliance program well designed? (referred to herein as "Design")
2. Is the program being applied earnestly and in good faith (i.e., effectively)? ("Implementation")
3. Does the compliance program work in practice? ("Operation")

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[32]FSG § 8B2.1, Comment 2(D).

[33]FSG § 8A1.2, Comment 3(E).

[34]DOJ, Criminal Division, *Guidance Document: Evaluation of Corporate Compliance Programs* (June 2020) (the "DOJ Guidance"). https://www.justice.gov/criminal-fraud/page/file/937501/download

By way of analogy, if the traditional core elements were like a shopping list of discrete compliance plan ingredients, much like a grocery shopping list, then the new framework is like a stew. No matter where the government dips its spoon (Design, Implementation, or Operation), each bite should contain multiple aspects of the former core elements.

a. Program Design

The Design analysis contains remnants of the following core elements: risk assessment processes,[35] policies and procedures,[36] training and communication,[37] confidential reporting,[38] and investigating.[39]

If we extend our food analogy, then Design would be like a recipe. The Design of a compliance program provides the written structural basis for its results. The DOJ Guidance provides that effective compliance programs should be designed with particularity, and they should be targeted to the types of misconduct that are most likely to occur within that organization.[40]

Two issues are deemed to be "critical factors" of Design:

(1) whether the program is designed for maximum effectiveness in preventing and detecting wrongdoing, and

(2) whether management is enforcing the compliance requirements or is tacitly encouraging or pressuring employees to engage in misconduct.[41]

Primarily, the government is looking toward risk assessment, monitoring, and auditing tools to address its specific identified risks. The compliance program should also establish appropriate benchmarks and metrics to measure the effectiveness of its efforts with respect to its risks.

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[35]Traditional element 5; *see* Attachment A for OIG list of traditional seven elements.

[36]Traditional element 1.

[37]Traditional element 3.

[38]Traditional element 5.

[39]Traditional element 7.

[40]DOJ Guidance, p. 2.

[41]DOJ Guidance, p. 2; JM 9-29.800.

b. Good Faith Implementation

Implementation is analogous to a cook working in the kitchen. This analysis determines whether the development and execution of the compliance program was diligent and faithful to the Design. The Implementation analysis includes the following traditional elements: compliance program autonomy and resources,[42] and the incentive and disciplinary programs.[43]

The Justice Manual distinguishes between a "paper program" and "one implemented, reviewed, and revised, as appropriate, in an effective manner."[44] As such, the DOJ Guidance places considerable emphasis here on the attitudes and actions of management. The government will also evaluate how compliance programs are funded, staffed, and integrated into upper management.

c. Effectiveness in Practice—Operation

Operation is like the presentation and taste of the final dish (i.e., does it taste good and pass the smell test?). The Operation analysis determines whether the compliance program works in practice. The Operation analysis includes remnants of these traditional elements: continuous improvement, testing, and review,[45] investigations of misconduct,[46] and analysis and remediation of misconduct.[47] government will perform its own qualitative and perhaps subjective assessment of compliance program effectiveness by determining whether the program's efforts are appropriate and its ongoing improvement efforts are meaningful.

d. Common Inflection Points

In the event the government detects or suspects misconduct, there are several common inflection points during which it is most likely to evaluate the Design, Implementation, or Operation of a compliance program. The evaluation

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[42]Traditional element 2.

[43]Traditional element 6.

[44]DOJ Guidance, p. 9; JM9-28.800.

[45]Traditional element 7.

[46]Traditional element 5.

[47]Traditional element 7.

may consider the state of an organization's compliance program at the time the misconduct occurred, at the present time, or both.[48]

The organization's compliance program may be considered at any time during the investigative and enforcement process. Assessments of compliance program effectiveness may be formal or informal, they may be rather subjective, and the approach is likely to vary from office to office and from case-to-case.

The evaluation of compliance program effectiveness is distinct from the decision to award cooperation credit. Although the foregoing factors may help demonstrate the effectiveness of a compliance program, they are not necessarily sufficient to qualify for cooperation credit.[49] Rather, the organization must also be able to demonstrate certain proactive measures to disclose and remediate the misconduct.[50]

The approach for determining whether to impose a corporate integrity monitor is also somewhat different. Although it considers some of the same factors, the Criminal Division engages in a cost-benefit analysis of the organization, considering, among other factors, whether the misconduct resulted from exploitation of an inadequate compliance program.[51]

IV. New or Expanded Expectations

In addition to changing the analysis framework, the recent governmental guidance provides new emphasis to certain compliance program functions. Although these matters had been mentioned in earlier treatises and are not new, they generally did not receive as much attention as other components, and compliance programs may not have emphasized their importance. The new guidance, however, places

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[48]DOJ Guidance, p. 13; JM 9-28.800.

[49]False claims act cooperation credit may not exceed an amount that would result in the government receiving less than its single measure of damages, lost interest, costs of investigation, and relator share.

[50]JM § 4-4.112, "Remedial Measures"; JM § 9-47.120(3)(b), (c); JM § 4-4.112, "Credit for Disclosure, Cooperation, and Remediation" and "Other Considerations"; *see also* JM § 9-47.120(1),(4); DOJ, Justice Manual, *Pursuit of Claims Against Individuals*, § 4-3.100(3) (November 2018).

[51]Benczkowski Memo, p. 2.

these issues at the forefront for all health compliance programs, and makes it clear that they will receive much closer scrutiny.

a. Management inadequacies and accountability

The DOJ Guidance places considerable emphasis on the managers and supervisors of those who commit misconduct. The first line of inquiry evaluates whether there were any management performance inadequacies that contributed to the issue. Additionally, the government determines whether the responsible managers and supervisors were held accountable for the misconduct that occurred under their supervision.

At the outset, a compliance program Design should include supplemental training for supervisors and the key gatekeepers of the organization's internal controls.[52] The training modules should include testing, and the organization should design appropriate corrective actions if an attendee fails all or part of the tests.[53]

Another area of focus is how executives have structured the organization's disciplinary and incentive processes. The organization should be able to demonstrate that its leadership has considered how those processes would impact compliance performance.[54]

The government further assesses whether the compliance program has been Implemented in good faith, or whether managers have tolerated greater compliance risks in pursuit of new business or revenues.[55] When managers expressly or tacitly encourage employees to act unethically, or when they create impediments to compliance professionals, the program has not been properly implemented.[56] Thus, the government reviews how senior and middle management professionals both express and actually reinforce their level of commit-

[52]DOJ Guidance, pp. 4-5.

[53]DOJ Guidance, p. 5.

[54]DOJ Guidance, p. 13.

[55]DOJ Guidance, p. 9.

[56]DOJ Guidance, p. 9.

ment to compliance.[57] It also recommends that organizations obtain input from all levels of employees to determine their understanding of management's commitment to compliance.[58]

The senior leaders who are responsible for funding and allocating resources also receive special attention. At the outset, the government assesses how the compensation, bonuses, disciplinary measures, and promotions of compliance professionals are determined.[59] Similarly, it considers whether compliance professionals are dedicated to compliance responsibilities or whether they have been burdened with other responsibilities.[60] The government also reviews how funding decisions may have contributed to acts of misconduct, and whether the organization's internal controls could have prevented misuse of those funds.[61]

If misconduct occurs, there should be a pattern of treating similar instances consistently.[62] The government evaluates whether the company publicizes its disciplinary actions, along with the reasons for that discipline, to other employees.[63] If discipline is not published, the government reviews whether that nondisclosure is based on valid legal concerns or whether it is an attempt to cover up and avoid scrutiny.[64]

When misconduct occurs, it is possible that there was a failure in oversight and supervision in the compliance program's Operation. Therefore, the government evaluates the role of managers and supervisors in failing to prevent the wrongdoing. There is an expectation that internal investigations seek to determine whether there were contributing lapses in oversight among supervisory managers and senior executives.[65] The organization should explore whether any previous opportunities to detect similar

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[57]DOJ Guidance, p. 5.

[58]DOJ Guidance, p. 15.

[59]DOJ Guidance, p. 13.

[60]DOJ Guidance, p. 11.

[61]DOJ Guidance, 2017 revisions, p. 4.

[62]DOJ Guidance, p. 12.

[63]DOJ Guidance, p. 12.

[64]DOJ Guidance, p. 12.

[65]DOJ Guidance, p. 15.

misconduct were overlooked, and the reasons for those missed opportunities.[66] If that is the case, the managers should have been held accountable for misconduct that occurred under their supervision.[67]

The DOJ Guidance also imposes accountability upon those managers and supervisors who are responsible for adopting policies and procedures or other internal controls. If the policies and procedures should have prevented the misconduct at issue, the government evaluates whether those policies and procedures were effectively implemented.[68] Any failures to either design effective internal controls or to implement them appropriately should result in some form of management accountability.[69]

b. Data Analytics

The DOJ Guidance emphasizes the importance of data analysis in compliance efforts, and some practitioners maintain that predictive analytics may be an industry-wide expectation for larger compliance programs. Broadly speaking, the government will assess how compliance data is collected and analyzed, how the compliance program reports that data to the organization's leadership, and how it tracks and resolves any identified issues through resolution.[70]

With respect to program Design, the primary consideration is whether the compliance program has been granted continuous access to operational data. The program should be enabled to test the organization's policies, controls, and transactions on a timely basis.[71] Periodic snapshot reviews may not suffice.[72]

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[66]DOJ Guidance, p. 17.

[67]DOJ Guidance, p. 17.

[68]DOJ Guidance, p. 16.

[69]DOJ Guidance, p. 16.

[70]DOJ Guidance, p. 16.

[71]DOJ Guidance, pp. 3, 12.

[72]DOJ Guidance, p. 3.

If there are any impediments to the compliance programs' access to data or other resources, the organization should demonstrate its efforts to overcome them.[73]

The data analysis should also be designed to capture sufficient information. The government will consider whether the compliance analytics overlooked key data points that might have alerted the organization to a problem.[74] Such metrics may not have fallen within the compliance purview, such as sales metrics or staff turnover.

Another Design consideration is whether the reporting metrics have been designed to foster effective compliance efforts. For example, the DOJ Guidance considers whether the risk management metrics will actually detect misconduct.[75] Moreover, the compliance program should apply timing metrics and other accountability measures to its investigations to help ensure that the organization responds appropriately.[76]

At the Implementation phase, the organization should periodically test its data analytics to ensure that they are sufficient to prevent or detect noncompliance.[77] The data analytics process should be refined as part of the program's ongoing continuous improvement.

An evaluation of the program's Operations will determine whether the organization previously overlooked any opportunities to detect misconduct and if so, the reasons for the omission.[78] A robust compliance data analysis program, using all appropriate data sources, can be instrumental in demonstrating operational effectiveness.

c. Mergers, acquisitions, and transactions

An organization often assumes the federal health program liabilities of any entity that it acquires or with which it merges. While the new owner might seek to distance itself from any previous noncompliance of the seller for purposes

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[73]DOJ Guidance, p. 12.

[74]DOJ Guidance, pp. 3, 12.

[75]DOJ Guidance, pp. 2-3.

[76]DOJ Guidance, pp. 5-6.

[77]DOJ Guidance, pp. 14-15; Benczkowski Memo, p. 2.

[78]DOJ Guidance, p. 17.

of discretionary sanctions, the DOJ Guidance makes it clear that any such disavowal is contingent upon the sufficiency of pre-transactional diligence.

At the outset, the organization is expected to engage compliance professionals who have the qualifications and experience to understand the proposed transactions and identify those activities that pose risk.[79] Any compliance professionals or outside counsel and consultants must be appropriately qualified and must use a generally accepted methodology.[80]

The organization must scope pre-closing diligence sufficiently and provide the time and budgetary resources to allow for meaningful review. The approach must be designed so that the diligence efforts are sufficient to identify any prior misconduct of the target.[81]

The government will also evaluate implementation by assessing whether the organization has ever stopped or modified a transaction after its compliance professionals raised concerns.[82] In this regard, the government could also scrutinize the diligence, efforts, and resources that have been applied to other transactions either before or after the acquisition at issue.

If misconduct or other noncompliance issues are discovered, the government will evaluate whether the new owner implemented improved policies, procedures, and other compliance controls to address the target issues after the transaction closed. The organization must also be able to demonstrate that it remediated and disclosed any past misconduct appropriately.[83]

Finally, the organization should be able to demonstrate that its compliance operations continue to monitor or audit newly-acquired targets after acquisition. The commercial sector is beginning to adopt similar expectations. Private equity investors, lenders, and representation and warranty insurers have all become more sophisticated about question-

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[79]DOJ Guidance, p. 10.

[80]DOJ Guidance, 2017 revisions, p. 7.

[81]DOJ Guidance, p. 8.

[82]DOJ Guidance, p. 11.

[83]DOJ Guidance, p. 8; Benczkowski Memo, p. 2.

ing the parties' underlying diligence and ensuring that buyers follow through on their promises to remediate any issues that were discovered during the transaction.

d. Third party risks and diligence

Because primary contractors and providers are ultimately responsible for the actions or omissions of their third-party vendors, the DOJ Guidance places increased emphasis on the organization's processes for delegation and outsourcing.

At the outset, there must be an appropriate business rationale for the determination to engage third parties.[84] The organization can only demonstrate the effectiveness of its program Design if it has documented the decision to subcontract at the time of contract inception.

The entity should also be able to establish through documentation that it investigated the representatives and the relationships of its third-party vendors before initiating the engagement.[85] Depending upon the nature and extent of the contract, such Operational vetting might be sufficient if it includes exclusion screening and standard background checks of the principals, but larger engagements and vendors will warrant a more thorough examination.

The DOJ Guidance further expects entities to continue monitoring third parties throughout the life of the contractual relationship. If any red flags are identified through such monitoring, the organization should address and remediate those matters and retain documentation of all such efforts.

e. Appropriate risk analysis

Risk analysis is integral to a compliance program's Design, Implementation, and Operation. As an initial matter, an organization should engage compliance professionals who have the qualifications and experience to understand and identify transactions and activities that pose risk.[86] Larger organizations should have compliance teams that are devoted to compliance matters, rather than bearing diverse responsibilities. Those professionals should then develop

[84]DOJ Guidance, pp. 4, 7.

[85]DOJ Guidance, pp. 4, 7.

[86]DOJ Guidance, p. 10.

compliance program metrics that are appropriate for detecting the particular types of misconduct that are specific to that organization.[87] As compliance resources are allocated, the program should devote more attention to high-risk transactions, rather than spending a disproportionate amount of time policing low-risk areas.[88]

The compliance team should develop and document a written rationale for the frequency and scope of its internal audits.[89] Compliance professionals should also consider carefully how investigations will be scoped, performed, and documented.[90] Organizations should also perform and document a periodic gap analysis of their compliance programs to identify opportunities for further development.[91]

The compliance program should also test and reassess its risk assessment tools and policies periodically and update them to reflect new developments as well as lessons learned.[92] If the compliance team determines that previous opportunities to detect misconduct were overlooked, it should assess the reasons for those missed opportunities and take steps to prevent recurrences.[93]

V. Practical Suggestions

Given the increased emphasis on the foregoing issues, compliance programs may need to adopt new policies and procedures or revise their existing ones to ensure appropriate coverage. Alternatively, health industry organizations may benefit from initiating a survey of all relevant operational policies from other business units outside the scope of the compliance program. Compliance programs can leverage such existing processes to fill in gaps until further compliance resources become available.

With respect to the new emphasis on management accountability, an organization should promote and encourage

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[87]DOJ Guidance, pp. 2-3.

[88]DOJ Guidance, p. 3.

[89]DOJ Guidance, p. 14.

[90]DOJ Guidance, p. 15.

[91]DOJ Guidance, p. 15.

[92]DOJ Guidance, p. 3.

[93]DOJ Guidance, p. 17.

compliance through its system of incentives and discipline going forward. However, it should move towards improved incentives, or better carrots. Employees respond to positive reinforcement. Incentives tend to improve attendance, job performance, and employee retention and commitment. These positive workforce attributes lead to lower liability, better financial results, and improved patient outcomes.

In those instances when misconduct has occurred, it is not uncommon for organizations to rationalize or overlook the involvement of their most profitable business units, and understandably so. Organizations want to keep their physicians and other high producers satisfied and productive. Similarly, managerial professionals under pressure to meet revenue targets may give lip service to compliance requirements while allowing employees to minimize them in practice. The government is aware of these pressures. Thus, CCOs should confer with business leaders to ensure that managers are willing to correct their high performing employees and that they are also held accountable through corrective action, performance and bonus reviews, or other appropriate measures.

In order to address the increased focus on third-party vendors and subcontractors, it may be necessary for health organizations to reassess the composition of their compliance committees or workgroups. These key compliance committees should include stakeholders who are responsible for procurement and contracting, acquisitions and joint ventures, and governmental relations.

There are practical ways to address the need for tailored risk analysis. Going forward, compliance professionals will need to work with the business units to identify key strategic risks. Auditing and monitoring should be collaborative, not confrontational or ambushed. This team approach will lead to measuring what matters and setting meaningful standards. Before finalizing an approach, talk to the business units about what is important. Business partners are more willing to participate and implement changes if they own the process and are partners in its development. Collaboration will improve performance and reduce risks. An added benefit is that the development of happier employees, who feel that they are part of a larger team or purpose, make it easier to respond to and remediate compliance lapses.

Compliance programs should be designed to offer training and education that is tailored to the organization's identified risks. Compliance programs need to constantly change their training to meet the current needs and risks impacting the company today and into the future. Training must be provided in different formats and languages. PowerPoint is fine but it cannot be the only solution. Compliance programs also need to adjust to the different learning styles of their audience. Compliance must meet the people where they are. Go to the floor and see what the staff are doing, answer their questions on their time, and develop trust-centered relationships between compliance professionals and staff.

Going forward, companies need to think strategically about how their policies work within the organization. Are the policies dynamic, living documents, or are they simply dusty documents that do not facilitate efficiency and growth or mitigate compliance? To avoid the latter, compliance programs need to work with their business partners to integrate compliance policies into standard operating procedures and review and update them regularly in response to business and legal changes.

Similarly, it will not be sufficient to say "no one ever called the hotline." Communication cannot be a passive activity. It will not be effective to wait for someone to come to the Compliance Office, pick up the hotline or read a newsletter. Compliance officers need to embed themselves in the business units, participate with the staff in their business meetings, and give staff a chance to have active and immediate conversations with the compliance department. Lines of communication will need to be tested and responses to reports tracked from beginning to end for efficient resolution.

Some CCOs struggle for resources because compliance programs may be perceived as cost centers rather than revenue-producing business lines. It may be helpful for these CCOs to collect baseline data for current educational needs, staff turnover, man-hours spent developing and implementing corrective action plans, employee litigation to challenge discipline, penalties or fines, and costs. An effective compliance program reduces risks and misconduct over time, thereby leading to less need for intensive or corrective training, less employee discipline and resulting grievances, less enforcement activity, and fewer costs of remediation.

Improvements in these benchmarks can become apparent when compared with baseline data.

Finally, there will be instances when, despite best efforts, the organization receives a visit from governmental authorities or a media inquiry about possible misconduct. The CCO or other official should be designated as a point of contact for all governmental notices and should be on the immediate contact list for other external inquiries. That person should receive supplemental training in the processes, standards, and expectations applicable to audits and investigations. More importantly, that individual should have access to all databases, records, and policies that might establish the compliance program's performance in accordance with the governmental guidance. Organizations often misapprehend the importance of retrieving and producing such documentation on a timely basis. If the designated response person already has familiarity with such information and can locate it readily, the organization can avoid many of the adverse findings that result from lack of documentation.

VI. Ethical Concerns for Compliance Counsel

Due to the complexity of the compliance function, particularly within the health industry, it is unsurprising that many health compliance officers are attorneys. The American Bar Association Model Rules of Professional Conduct (the "Model Rules"), upon which most states' ethical rules are based, address certain ethical issues that are commonly encountered in a compliance practice. The comparable rules in each jurisdiction can assist attorneys in navigating the inevitable nuances and uncertainties that arise out of health care governance.

a. Organization as a Client

Given that most health industry providers are business entities, it is critical to examine the role of lawyers within an organization. A lawyer employed or retained by an organization represents the entity and must proceed in its best interests.[94] Counsel may also represent the organization's directors, officers, employees, or other constituents as long

[94]Texas Disciplinary Rules of Professional Conduct ("Texas Rule") 1.12(a); *see also* American Bar Association, Model Rules of Professional

as the entity consents in accordance with the conflict of interest rules and the consent is granted by someone who is not the individual being represented.[95]

Role clarification becomes essential in compliance matters for several reasons. First, the duty of confidentiality only applies to communications between the lawyer acting in his or her organizational capacity and the organization's constituents.[96] Organizational constituents are defined to include officers, directors, employees, shareholders, members, and others in equivalent positions or capacities.[97]

Business clients may not fully understand how the role of a lawyer or the attorney client privilege works. Thus, it may be incumbent upon the CCO to clarify the capacity in which he or she is acting so that the constituents understand which privileges and duties may or may not apply. If a matter concerns "policy and operations," as many compliance issues do, it may be outside the scope of legal representation for privilege and confidentiality purposes.[98]

The duty of confidentiality prohibits an attorney from disclosing both privileged and unprivileged client information. Unprivileged client information means all information relating to the client acquired by the lawyer during the course of or by reason of the representation.[99] Because healthcare compliance officers may have affirmative duties to disclose or report certain matters, this can create an unworkable tension for an attorney CCO unless the constituents have been reminded of the CCO's organizational capacity and the organization has structured its operations accordingly.

Role clarification is also essential in internal investigations, which may involve allegations against constituents. Any lawyer, whether in-house or external, must explain the

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Conduct ("Model Rules"), Rule 1.13(a) (2018). We cite our controlling authority and recommend that each practitioner review the adopted rules in his or her jurisdiction.

[95]Texas Rule 1.12 Comment 5.

[96]Texas Rules 1.05, 1.12 Comment 3, 2.02 Comment 4.

[97]Texas Rules 1.12 Comment 2.

[98]Texas Rules Preamble Comment 12, 1.01(a), 1.12 Comment 6.

[99]Texas Rule 1.05; *see also* Texas Ethics Op. 384; Model Rule 1.6 Comment 3.

identity of the client when the organization's interests are or may become adverse to those of the constituent, and the lawyer cannot represent the constituent.[100]

Disclosures to interviewees or other constituents should also advise them that their communications may not be privileged.[101] Although the organization can assert privilege or confidentiality over all internal interviews performed by legal counsel, that privilege may be waived if the entity later decides to disclose wrongdoing or report findings of noncompliance.

b. Scope of Representation

To the extent an organization chooses to engage an attorney as its CCO or other compliance professional, the ethics rules clearly support this position. The organization has ultimate authority to determine the objectives to be served by legal representation, within the limits imposed by law, the lawyer's professional obligations, and the agreed scope of representation. Within those limits, a client also has a right to consult with the lawyer about the general methods to be used in pursuing those objectives.[102]

Although the client has a right to define the scope of legal representation, the compliance effectiveness guidance requires that internal investigations and reviews be scoped appropriately. If a client requests that compliance counsel provide purely technical advice in a situation that may warrant further factual inquiry, the lawyer should determine whether that client is experienced in legal matters. The lawyer may rely upon the scoping decisions of its more sophisticated and experienced clients. If the lawyer is concerned, however, that the client may not be as experienced, he or she may have an affirmative responsibility to advise that client that there may be material considerations beyond the legal authorities or the client's stated objectives.[103]

c. Roles of a Lawyer

Whether an attorney is acting as General Counsel, CCO,

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[100]Texas Rule 1.12(e).

[101]Texas Rule 1.12 Comment 4.

[102]Texas Rule 1.02 Comment 1.

[103]Texas Rule 2.01 Comment 3.

or both, health compliance practices involve a broad array of issues, and counsel may fulfill various roles for the client. The Model Rules recognize four distinct roles of a lawyer, each of which is likely to arise in compliance matters: Advisor, Evaluator, Advocate, and Negotiator.

The most inward-facing role is that of the advisor. An Advisor "provides the client with an informed understanding of legal rights and obligations and explains their practical implications."[104]

Ethics rules require lawyers to "exercise independent professional judgment and render candid advice."[105]

One occupational hazard for compliance practitioners is the risk of suffering retribution after delivering bad news. Discussions about investigative findings, root causes of noncompliance, remediation and repayment, employee termination and discipline, or risk assessment can be uncomfortable and result in marginalization of the compliance team. Nevertheless, lawyers in the compliance field must face such discussions directly. The Rules provide:

> Legal advice often involves unpleasant facts and alternatives that a client may be disinclined to confront. In presenting advice, a lawyer endeavors to sustain the client's morale and may put advice in as acceptable a form as honesty permits. However, a lawyer should not be deterred from giving candid advice by the prospect that the advice will be unpalatable to the client.[106]

The updated compliance guidance emphasizes repeatedly the importance of Board and management engagement and oversight. Compliance counsel may become aware of matters involving misconduct, concerns arising during due diligence, or inadvertent violations that have not been escalated from the business team to the governing body and senior leaders. Normally, attorneys do not have an obligation to render unsolicited advice. However, a lawyer may have a duty to offer advice to the client if it finds during the course of representation that the client proposes action that is likely to

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[104]Texas Rules Preamble Comment 2.

[105]Texas Rule 2.01; *see also* Model Rule 2.1.

[106]Texas Rule 2.01 Comment 1.

result in substantial adverse legal consequences to the organization.[107]

When a lawyer acts as an Evaluator, he or she examines the client's affairs and reports about them to the client or others.[108] This role is both internal and outward facing. In the compliance context, the role of evaluator may arise during transactional due diligence or through internal audits and investigations on issues that may require disclosure.

The duties of confidentiality and loyalty apply to an evaluation engagement.[109] Thus, the evaluation must be compatible with the lawyer's scope of engagement, and any disclosures must be issued only after the client consents.[110]

The recent compliance guidance emphasizes the need for qualified persons to conduct due diligence before entering into joint ventures or other transactions, whether they are in-house or outside counsel. In those engagements, consent to disclose the results may be implied because due diligence inherently requires the disclosure of certain information. If the disclosure could have a material adverse effect on the client, however, a lawyer should explain the risks of disclosure and obtain consent prior to reporting to third parties.[111]

The role of Evaluator applies only to the lawyer's client. Appointed special counsel and attorneys who act as external reviewers or outside monitors by the government or other third parties are not Evaluators. Lenders and insurers may also engage health compliance counsel to review proposed transactions before they fund loans or issue coverage. No duties of confidentiality or loyalty apply to non-clients.[112] Thus, those lawyers should inform the organization's constituents that they do not represent the organization and that their communications will not be privileged. Furthermore, any reports to be delivered to external parties should clearly indicate the role of the attorney and whether the target was a client.

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[107]Texas Rules Preamble Comment 12, 2.01.

[108]Texas Rules Preamble Comment 2.

[109]Texas Rule; *see also* Model Rule 2.3(c), Comment 2.

[110]Texas Rule; *see also* Model Rule 2.3(a), (b).

[111]Texas Rule; *see also* Model Rules 1.0(e), 1.6(a), 2.3 Comment 5.

[112]Texas Rule; *see also* Model Rule 2.3 Comment 2.

An attorney acting in the role of Advocate zealously asserts the client's position under the rules of the adversary system.[113] This role is focused on external communications, and it only applies when the lawyer represents the client in an official hearing or meeting of a governmental agency in which evidence or arguments will be presented.[114]

Formal proceedings are not limited to judicial conflicts or contested administrative hearings. Compliance practitioners may be called upon to represent the organization in more informal appeals of adverse audits, facility surveys, penalty assessments, or other administrative sanctions.

In such instances, lawyers must disclose their representative capacity, exercise candor toward the judge, agency, or fact finder, be fair to opposing parties and counsel, and refrain from *ex parte* communications or other behavior that could undermine the tribunal's appearance of impartiality.[115]

Attorneys cannot defend such proceedings or controvert findings on frivolous grounds. There must be some basis in law or fact for all defenses, or alternatively, a good faith basis that the existing law should be extended, modified, or reversed.[116] While outside counsel can often convince organizations to abandon frivolous defenses on cost-effectiveness grounds, internal compliance officers or counsel may face increasing pressure to advance non-meritorious positions. This ethical rule can help persuade business owners to look beyond the immediate exigencies and adopt a strategy that will protect the organizational reputation during the proceedings and beyond.

These same concerns apply to governmental enforcement attorneys. For example, the Brandt and Cleary memoranda were issued in part to ensure that enforcement counsel limited their claims and defenses to those statutes and regulations that had been duly promulgated. While the force and effect of subregulatory policy may have been less clear in the past, these memoranda clarify the scope of proper enforcement. Enforcement theories that exceed that scope

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[113]Texas Rule; *see also* Model Rules Preamble Comment 2.

[114]Texas Rule; *see also* Model Rule 3.9 Comment 3.

[115]Texas Rules 3.03, 3.04, 3.05; *see also* Model Rule 3.9.

[116]Texas Rule 3.01 Comments 1, 2, and 3.; *see also* Model Rule 3.1.

could be subject to ethical complaints against enforcement attorneys for asserting frivolous claims.[117] Moreover, prosecutors are subject to special ethical responsibilities to see that justice is done and not simply to be an advocate.[118] In the event a compliance investigation involves a parallel criminal case, it may be worthwhile to review these ethical safeguards.

When a compliance lawyer acts as a Negotiator, he or she seeks a result that is advantageous to the client but consistent with the requirements of honest dealing with others.[119] This role applies to representation before agencies in matters that do not involve formal adversarial proceedings, such as facility licensing negotiations, filing of required reports, or early-stage governmental investigations.[120]

A lawyer cannot make a false statement of material fact or law to a third person.[121] Additionally, an attorney cannot fail to disclose a material fact if disclosure is necessary to avoid assisting the client in committing fraud.[122]

Unlike the Advocate, who must disclose adverse controlling authority or correct previous fact misstatements, a Negotiator's disclosure obligations to others are more limited. The attorney generally has no affirmative duty to disclose all relevant facts.[123] In general, it is acceptable under the rules to withhold certain information during negotiations, such as estimates of price or value, assessments of favorable settlement terms, or most undisclosed principals.[124] The generally accepted practices of negotiation recognize that such statements need not be taken as statements of material fact.

Unless negotiations involve discussions that are commonly understood to include posturing and puffery, compliance counsel should be mindful of the laws and ethical rules relating to misrepresentation. For example, attorneys should

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[117]Texas Rule 3.01. Such challenges would subject to applicable immunity principles.

[118]Texas Rule 3.09 Comment 1.

[119]Texas Rule; *see also* Model Rules Preamble Comment 2.

[120]Texas Rule; *see also* Model Rule 3.9 Comment 3.

[121]Texas Rule; *see also* Model Rule 4.1(a).

[122]Texas Rule; *see also* Model Rule 4.1(b).

[123]Texas Rule 4.01 Comment 3; *see also* Model Rule 4.1 Comment 1.

[124]Texas Rule 4.01 Comment 1.

avoid affirming the statement of another person that the lawyer knows to be false. Given the subjectivity of this prohibition, compliance practitioners – particularly those who serve as CCOs or other compliance professionals – will want to consider their affirmative reporting obligations in determining what constitutes a misleading omission.

d. Duties to Report

The express affirmative legal duties to report healthcare noncompliance are somewhat less extensive than might be expected when considering the overall extent of health regulation and the vast scope of health items and services rendered on a daily basis. Perhaps the most important affirmative duty is the federal statutory requirement to report and repay provider overpayments within sixty (60) days of identifying them.[125] The failure to report constitutes a reverse false claim under the federal False Claims Act and subjects the organization to the same multiple damages and penalties as if it had filed a false claim.[126] Although this obligation seems straightforward, there is room for interpretation as to when an overpayment has been "identified" or even whether certain payments meet the materiality threshold for constituting an overpayment or other obligation to repay.[127] The provider also has a certain amount of discretion about the form and recipient of any such report.[128]

The OIG has long recommended that compliance training programs include substantive material on employees' duty to report misconduct within the organization, and it has encouraged external reporting to the government.[129] For example, the Self-Referral Disclosure Protocol and the Voluntary Self-Disclosure Protocol both incentive disclosures by committing to minimize multiple damages and to consider cooperation

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[125]42 U.S.C. § 1320a-7k(d); 42 C.F.R. § 401.305; *see also* 42 U.S.C. § 1395nn(g)(2), 42 C.F.R. § 411.353 (establishing affirmative duty to refund payments for designated health services in violation of Stark Law).

[126]31 U.S.C. § 3729(a); 42 U.S.C. § 1320a-7a(a)(10).

[127]42 C.F.R. § 401.305(a); 81 Fed. Reg. 7659-63.

[128]42 C.F.R. § 401.305(d).

[129]See, e.g., OIG Open letter April 2000? 64 Fed. Reg. 54031, 54043 (Oct. 5, 1999); 63 Fed. Reg. 45076, 45083 (Aug. 24, 1998); 63 Fed. Reg, 8987, 8995 (Feb. 23, 1998).

credit and other mitigating factors in resolving Stark Law and Anti-Kickback Statute violations.[130] Although these efforts may promote reporting, they do not establish independent legal affirmative duties.

Other express affirmative reporting duties arise with far less frequency. Providers, payors, governmental entities, and accrediting organizations must report certain adverse or exclusionary determinations to the National Practitioner Data Bank, many of which do not reach finality until some form of Due Process has been exhausted.[131] There may be additional federal, state, or local reporting requirements arising in certain circumstances, such as the provision of particular items or services, adverse events arising in clinical trials or occurring in inpatient and residential facilities, and incidents involving individuals who are minors, disabled, or elderly.[132]

The government, however, does not limit its expectations to these express affirmative duties. Rather, it has asserted on multiple occasions that concealment of certain actions may constitute a criminal or civil offense.[133] The government has even relied upon professional standards to support its contention that a third party had an affirmative duty to report.[134] While such assertions have not always succeeded, they illustrate the importance of ethical guidance in determining how to remediate identified instances of noncompliance.

In-house attorneys who also serve as CCOs or compliance professionals should balance the tension between their duty

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[130]ACA 6409 (Stark); 63 Fed. Reg. 58399, 58400 (Oct. 30, 1998).

[131]Social Security Act Title VII and Sections 1921, 1128E.

[132]This chapter does not purport to offer a comprehensive exploration of affirmative duties to report, which will vary widely based upon each organization's sub-industry, service lines, and governmental program grants and contracts. Organizations should obtain individualized legal advice to determine their affirmative reporting obligations.

[133]18 U.S.C. § 1035(1) (falsity through concealment); U.S. Calhoon, 97 F.3d 518 (11th Cir. 1996); 18 U.S.C. § 4 (misprison of felony); 18 U.S.C. § 2 (criminal aiding and abetting); 18 U.S.C. § 31 (conspiracy to defraud).

[134]*See, e.g., U.S. ex rel Schilling v. KPMG Peat Marwick LLP*, Cause No. 98-901-c0v-t-17F (M.D. Fl.); *U.S. v. Augustine Medical Inc., et al*, Cause No. Crim 03-30023-GPM (Indictment filed Jan. 24, 2003). U.S. v. Anderson, 55 F.Supp.2d 1163 (D. Kan. 1999).

to report and the duty of confidentiality owned to a client. These lawyers may not be able to assert that their efforts as a CCO constitute attorney work product or are otherwise privileged. Such conflicts can be mitigated somewhat by clearly distinguishing when the lawyer is acting as the CCO and when he or she is serving as legal counsel. It is also possible that the client has implicitly consented to some disclosures in accordance with the ethics Rules by engaging that lawyer as a CCO, knowing that compliance professionals bear certain affirmative reporting obligations. These approaches, while helpful, will not be sufficient to address every such conflict.

Even if a lawyer is acting solely in the role of legal counsel, he or she will have some reporting obligations. Attorneys representing an organization must take affirmative actions upon learning—within the scope of representation—that a person has committed or intends to commit a violation of law which reasonably might be imputed to the organization and is likely to result in substantial injury to the organization.[135]

The Rule comments distinguish between client decisions that the lawyer believes to be imprudent, which should generally be accepted, and decisions that are likely to create substantial injury to the organization or violate the law or other legal obligations.[136] In the latter event, an attorney must begin by taking measures within the organization unless other law or rules require prior external disclosure. If the initial internal efforts fail, the lawyer may continue escalating up to the Board or other governing authority.[137]

Such discussions cannot advise the organization to engage in conduct that the lawyer knows to be criminal or fraudulent, and the lawyer cannot assist the client in committing such conduct. The lawyer should discuss the legal consequences of the proposed conduct and help the client determine in good faith the validity, scope, meaning, or application of the law.[138]

If the Board insists upon action that is clearly a violation

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[135]Texas Rule 1.12(b); *see also* Model Rule 1.13 Comment 3.

[136]Texas Rule 1.12(c), Comment 6.

[137]Texas Rule 1.12(c).

[138]Texas Rule 1.02(c).

of law, the lawyer may be required to withdraw from further representation.[139] Withdrawal is required if representation will result in a violation of the rules of professional conduct or other law. Withdrawal is permissible if the client persists in action the lawyer believes to be criminal or fraudulent, the client has misused the lawyer's services, or the client insists upon taking action with which the lawyer has a fundamental disagreement.[140]

The attorney must disclose to the court If the client engages or intends to engage in criminal or fraudulent conduct related to an adjudicative proceeding, the attorney must disclose such conduct to the court.[141] A lawyer may also be required to disclose to a third person, if necessary, to avoid assisting a criminal or fraudulent act by the client.[142]

The lawyer may permissibly reveal confidential information that is related to the representation to the extent such disclosure is reasonably necessary to prevent reasonably certain substantial injury to the organization if the disclosure is in accordance with the scope of representation and confidentiality rules.[143] The ethics rules do not specify any particular recipient of the disclosure, and such determinations will depend upon the facts. Although the parameters will vary in each jurisdiction, permissible disclosures generally include those that the attorney reasonably believes are necessary to prevent the client from committing a crime or fraud that is likely to result in death or serious injury, to prevent the client from committing other criminal or fraudulent acts, or to rectify the consequences of a client's criminal or fraudulent act involving the lawyer's services.[144]

Most compliance matters will not rise to the level of requiring external disclosures over a client's objections. Counsel may simply have to accept a client's imprudent decisions, go home, and reconsider his or her life choices. However, in

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[139]Texas Rules 1.12(d) and Comment 3, 1.15(a) and Comment 2; *see also* Model Rule 1.16.

[140]Texas Rule 1.15 Comment 7

[141]Texas rule 3.03(a)(2); *see also* Model Rule 3.3(b).

[142]Texas Rule 4.01(b); *see also* Model Rule 4.1(b).

[143]Texas Rules 1.02, 1.05, 1.12 Comment 7.

[144]Texas Rule 1.05(c), (d), Comment 19.

those situations warranting disclosure, state bar associations may provide staff ethics attorneys who can help practitioners navigate the options. It could be worthwhile to secure legal advice on an anonymized basis from such specialized advisors or other qualified attorneys. Such conversations are handled discretely and can provide great reassurance and guidance during stressful events.

V. Summary

In summary, the traditional seven elements of compliance programs no longer provide a sufficient basis by which to assess the effectiveness of compliance programs. Many of the new expectations are not new concepts, but they have been elevated from guidance discussions into a cohesive set of express requirements or factors to be considered in a more uniform fashion. The new guidelines are not always adequate to address ethical concerns that may apply to compliance counsel, and attorneys will need to exercise caution as they define their roles and scope of work.