

Compliance Program Trends 2021

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Compliance Program Trends

- **We will look at trends affecting the various elements of compliance programs. From codes of conduct to the CARES Act.**

Codes of Conduct

- **Codes of conduct are becoming longer, easier to understand and better illustrated.**
- **They are not becoming better read. Why?**

Codes of Conduct

- **As an employee who is not in compliance, why read it?**
- **If I have to sign it, I will sign it.**
- **But unless it is **useful**, I am not going to read it with care.**

Codes of Conduct

- **While the code of conduct is the documentary cornerstone of the program, we should not rely on the code as a primary educational tool.**

Policies

- **Policy development and policy management are two of the weakest areas in compliance program development.**

Policies

- **In larger organizations, there is often a local versus centralized control of policies issue that leads to duplicative and sporadic update of policies.**

Policies

- **Management at locations wishes to manage the policies for that location, while compliance and legal want policies to be centralized and centrally managed.**

Policies

- **You need both a Policy on Policies and someone charged with overseeing it.**

Policies

- **It has to be possible for employees to read and follow the policies.**
- **Employees cannot be held accountable for policies they can't understand.**

Exclusion and Background Checks

- **Background and exclusion checks – more people and more frequently.**

Exclusion and Background Checks

- **Some organizations *repeat* background checks periodically, such as every five years, and upon key events such as promotion to a compliance sensitive position.**

Exclusion and Background Checks

- You may discover wrong-doing which has not yet resulted in an exclusion and also issues relating to patient protection.**

Relationship to Internal Audit

- **Coordination between Internal Audit and Compliance has improved with some activities such as risk assessment and monitoring corrective actions being conducted conjointly.**

Internal Reporting

- **More and more organizations supplement the hotline with internet based reporting and management certification.**

Internal Reporting

- **Management certification is a process by which all managers above a certain level are asked to periodically certify that they have reported all compliance issues of which they are aware.**

Internal Reporting

- **With the government emphasizing prosecution of individuals, managers want to be sure that their direct reports are not sitting on something.**

Internal Reporting

- **More organizations are publicizing the direct dial number of the Compliance Office.**
- **Higher level employees and managers are more likely to report directly than to use a hotline.**

Internal Reporting

- **While most organizations have a non-retaliation policy for compliance reports, this policy continues to be seldom enforced.**

Internal Reporting

- **Survey research reveals that most employees believe that they know about instances of retaliation.**
- **When is the last time that someone has been disciplined for retaliation?**

Internal Reporting

- **While it is hard to enforce a strict non-retaliation policy, doing so is the key to managing your main risk which is whistle-blower risk.**

Corrective Action

- **More attention to formalizing the corrective action process (for compliance infractions) including a monitoring plan.**
- **This is an area in which improvement – especially on the monitoring side – is much to be desired.**

Corrective Action

- **If you have an internal audit schedule, add corrective actions to the audit schedule on a regular schedule.**

COI

- **Increased rigor and scope of COI processes.**
- **Better monitoring of COI mitigation plans.**

COI

- **There is still some resistance to the compliance function overseeing COI even though it is a clear compliance risk (Stark, AKS) area.**

Education

- **The trends in compliance training are mostly negative.**
- **Less live training; less creativity in online modules.**

Education

- **Little or no evaluation of the effectiveness of the training modules.**
- **It does not make sense to use an hour of all employees' time yearly without trying to find out if there is any benefit.**

Risk Assessment

- **Compliance **risk** assessment is getting more attention but methodology is weak.**
- **Over dependence on OIG work plan, which is NOT where big investigations originate.**

Program Assessment

- **Compliance program assessment is getting more attention but also plagued by**
 - **Poor methodology**
 - **Lack of bench marking**
 - **Lack of measures**
 - **Inconsistency over time**

General Observations

- **Migrating away from compliance and towards integrity in terms of communicating the program.**

General Observations

- **Difficulty in understanding compliance as part of a system of internal controls (COSO – Committee of Sponsoring Organizations of the Treadway Commission).**

General Observations

- **Fewer CIAs but more demanding terms on those that are implemented including external monitors beyond the IRO.**

General Observations

- **More “local” compliance program representatives, paid and dual hats.**

General Observations

- **Limited understanding of areas in which new organizations forms such as ACOs are likely to create risks.**

General Observations

- **More business line or functional compliance plans – home care, behavioral, HIM, privacy, pharmacy, lab, physician practices and so on.**
- **Where the risks in an area are unique, this is a good practice.**

Compliance Risks

- **Not much chance of covering comprehensively as real risk comes from FCA actions that are hard to predict unless they mimic an existing FCA action.**

Compliance Risks

- **I will discuss some of the risks related to the CARE ACT – Coronavirus Aid, Relief and Economic Security Act.**
- **Advertised as no-strings-attached funding, but of course there are strings when you accept federal dollars.**

Compliance Risks

- **\$100 billion relief to support health care-related expenses or lost revenue due to COVID-19 and testing/treatment**
- **Both general and targeted allocations (high impact areas, treatment of uninsured, etc.)**
- **These are payments, not loans with forgiveness criteria, but retaining the payments requires compliance with Terms & Conditions**

Compliance Risks



DEPARTMENT OF HEALTH & HUMAN SERVICES

Acceptance of Terms and Conditions

If you receive a payment from funds appropriated in the Public Health and Social Services Emergency Fund for provider relief (“Relief Fund”) under Public Law 116-136 and retain that payment for at least 90 days without contacting HHS regarding remittance of those funds, you are deemed to have accepted the following Terms and Conditions. Please also indicate your acceptance below. This is not an exhaustive list and you must comply with any other relevant statutes and regulations, as applicable.

Your commitment to full compliance with all Terms and Conditions is material to the Secretary’s decision to disburse these funds to you. Non-compliance with any Term or Condition is grounds for the Secretary to recoup some or all of the payment made from the Relief Fund.

Compliance Risks

- **Example Terms & Conditions**
 - **Cannot be used to reimburse expenses/losses that have been reimbursed from other sources, or which other sources are obligated to reimburse**
 - **E.g.: Insurance policy subsequently reimburses expenses, must repay funds from HHS**

Compliance Risks

- **Funds cannot be used for certain purposes**
 - **E.g.: Excessive executive pay, gun control advocacy, abortion, lobbying, embryo research, promotion of legalization of controlled substances, pornography, human trafficking, and more**

Compliance Risks

- **Warnings and Purported Effect**
 - **T&C warning: Any deliberate omission, misrepresentation, or falsification of information in application or future reports can result in criminal civil, or administrative penalties**

Compliance Risks

- **The T&C expressly state that a provider’s “commitment to full compliance with all Terms and Conditions is material to the Secretary’s decision to disburse these funds to you.”**
 - **Government’s attempt to shore up “materiality” argument for future FCA litigation; uncertain success**

Compliance Risks

- **Enforcement**
 - **Special Inspector General for Pandemic Recovery (SIGPR)**
 - **Modeled after SIGTARP following 2008 financial collapse**
 - **SIGTARP investigations resulted in 380 convictions (97 percent conviction rate) and recovery of > \$11 billion**

Compliance Risks

- **Attorney General William Barr directed all U.S. Attorneys to “prioritize the detection, investigation, and prosecution of all criminal conduct related to the current pandemic”**
 - **“[W]e will deploy the False Claims Act against those who commit fraud related to the various COVID-19 stimulus programs...” – Ethan Davis, Principal Deputy AAG for DOJ Civil Division (June 26, 2020)**

Compliance Risks

- **There are other compliance risks related to Covid-19 such as excessive hoarding and price gouging which are illegal under the Defense Production Act.**

Compliance Risks

- **You must create detailed documentation now to avoid these future compliance risks.**

Compliance Risks

- **Retaliation based lawsuits.**
- **Even when a claim does not succeed, the retaliation protection provisions of FCA can become an FCA issue.**

Compliance Risks

- **Poor understanding and systematization of quality measures and ways in which they can be manipulated.**
- **This is a 100% certain risk area as OIG emphasizes quality audits.**

Compliance Risks

- **Be attentive to risks revealed by actions involving other organizations.**
- **The government doesn't invent but it does replicate.**

Compliance Risks

- **Always think about risk in terms of correlating risks and controls. You can't eliminate risks but you can control for them.**
- **This is how you manage the risk profile strategically.**

Compliance Risks

- **Remember that your risks mostly likely come not directly from the government, but from a whistle blower.**
- **That whistle blower is likely one of your employees, contractors or physicians.**

Compliance and Quality

- **The future of compliance is at the nexus of compliance and quality as more and more reimbursement is quality based.**
- **One of the best things a compliance professional can do today is get inside the quality measures used by their organization.**