



1

DISCLAIMER

- This PPT is accurate and complete as of the date of this presentation. Presenter bares no responsibility for changes in regulatory requirements, guidelines, statutes, laws, etc. after the date of this presentation.
- It is not my intent to cover every slide as the majority of these will be used for reference in the future.
- This PPT is meant to help you understand the ins and outs of regulatory compliance, the appeals process, and then how to use the information to successfully defend your providers', practice and claims.
- At the end of the day I am a physician advocate and my first responsibility is to my clients to ensure due process and a fair shake and level playing field.



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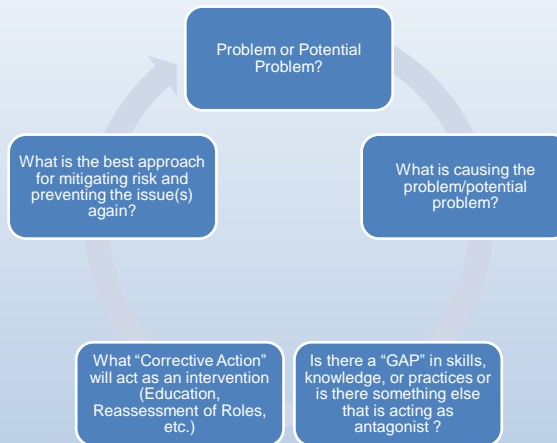
GAP ANALYSIS OVERVIEW

A GAP Analysis measures existing policies and SOPs against industry standards or “Best Practices” in addition to applicable laws, acts, regulations, etc. Results typically indicate gaps and/or deficiencies in the compliance program, including but not limited to potential regulatory violations. Identifying gaps, allows one to take corrective action and mitigate ongoing and/or future risks to the business.



3

THE GAP ANALYSIS



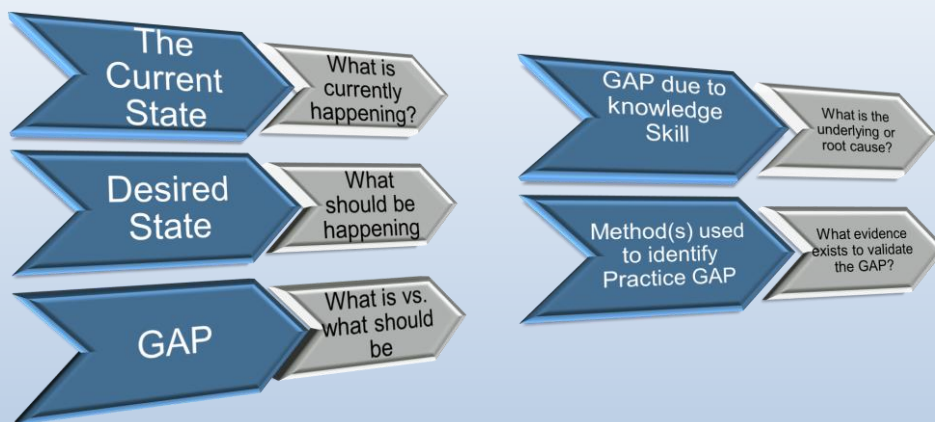
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THE GAP ANALYSIS

- A GAP Analysis and Needs Assessment are almost synonymous with the exception that the GAP allows for more standardization of processes in determining the “gap-of-knowledge” is.
- We use the GAP to justify the necessity for education or remedial education in high-risk areas to provide guidance in identifying the difference between current knowledge, skills, and/or practice and what the desired best practice/outcomes are.
 - Compliance must be absolute for all providers of health care regardless of setting, specialty or insurance participation



THE STEPS OF A GAP ANALYSIS



RISK IDENTIFICATION

- Risk comes in various types and varying degrees.
- Regardless of the “Type of Risk” ignoring it or wishing it away is not how you mitigate it.
- Risk can be identified through various means such as
 - inspections,
 - citations,
 - audits,
 - information logs,
 - training; and
 - laws and regulations.
- Risks associated with third-party relationships, including but not limited to suppliers and service providers are important.
- Looking at the organization holistically will aid in the process of determining the particular category(s) to focus on as part of the GAP analysis.



RISK MITIGATION

- Mitigation of Risk is critical to covering your “ass-ets”.
- Choosing to forge ahead with an investigation and/or risk analysis is how an organization demonstrates “Good-Faith” and the effectiveness your culture has on compliance.
- Working to cure breaches and/or issues within the operations works towards reducing regulatory fines, scrutiny and better positions the organization for those unexpected visits.
- Acting in reckless disregard or in deliberate ignorance of the truth is what causes organizations prolonged legal issues.



BUILDING OF AN EFFECTIVE COMPLIANCE PROGRAM

- Effective compliance programs include appointed compliance officer persons and/or a committee depending on the size of the organization.
- A Compliance Officer engages in the review of allegations and or concerns raised for potential problems as part of a GAP Analysis.
- The Compliance Officer initiates corrective action in addition to ensuring open lines of communication with all employees and being transparent throughout the process without waiving privilege.
- The GAP process often brings not so evident issues to the surface creating heartburn for those organizations lacking human and financial capital to deal with the fallout.
- Due to complex laws and regulations many companies lack internal resources to perform a proper gap analysis and as such things get swept under the rug with the hopes our little secret never slips out in to the open.



COMPLIANCE CONSIDERATIONS

- As compliance officers we try to determine when and under what circumstances to have compliance programs undergo outside review, and what the review process should look like.
- OIG guidance calls for periodic independent reviews of compliance programs, and the US Sentencing Commission calls for companies to “evaluate periodically the effectiveness of the organization’s compliance and ethics program.”
- This standard highlights that compliance should be checked to verify it’s actually working as designed.
- In June 2020 the DOJ Criminal Division released its updated “Evaluation of Corporate Compliance Programs,” which puts compliance officers on notice about what the DOJ expects to see with compliance programs.
- There are huge differences between “compliance gap analysis” and “compliance effectiveness evaluations” in cost and results outcomes.



THREE CRITICAL QUESTIONS

- “Is the corporation’s compliance program well designed?”
- “Is the program being applied earnestly and in good faith?” In other words, is the program adequately resourced and empowered to function effectively?
- “Does the corporation’s compliance program work” in practice?
 - Justice Manual (JM) 9-28.800



IS THE CORPORATION’S COMPLIANCE PROGRAM WELL DESIGNED?

- The “critical factors in evaluating any program are whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in misconduct.” JM 9-28.800.
- Prosecutors should examine “the comprehensiveness of the compliance program,” JM 9-28.800, ensuring that there is not only a clear message that misconduct is not tolerated, but also policies and procedures – from appropriate assignments of responsibility, to training programs, to systems of incentives and discipline – that ensure the compliance program is well-integrated into the company’s operations and workforce.



RISK ASSESSMENT

- The starting point for a prosecutor's evaluation of whether a company has a well designed compliance program is to understand the company's business from a commercial perspective, how the company has identified, assessed, and defined its risk profile, and the degree to which the program devotes appropriate scrutiny and resources to the spectrum of risks.
 - In short, prosecutors should endeavor to understand why the company has chosen to set up the compliance program the way that it has, and why and how the company's compliance program has evolved over time.
- Prosecutors should consider whether the program is appropriately "designed to detect the particular types of misconduct most likely to occur in a particular corporation's line of business" and "complex regulatory environment[]." JM 9-28.800.3
 - For example, prosecutors should consider whether the company has analyzed and addressed the varying risks presented by, among other factors, the location of its operations, the industry sector, the competitiveness of the market, the regulatory landscape, potential clients and business partners, transactions with foreign governments, payments to foreign officials, use of third parties, gifts, travel, and entertainment expenses, and charitable and political donations.
- Prosecutors should also consider "[t]he effectiveness of the company's risk assessment and the manner in which the company's compliance program has been tailored based on that risk assessment" and whether its criteria are "periodically updated."
 - See, e.g., JM 9-47-120(2)(c); U.S.S.G. § 8B2.1(c) ("the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement [of the compliance program] to reduce the risk of criminal conduct").
- Prosecutors may credit the quality and effectiveness of a risk-based compliance program that devotes appropriate attention and resources to high-risk transactions, even if it fails to prevent an infraction.
 - Prosecutors should therefore consider, as an indicator of risk-tailoring, "revisions to corporate compliance programs in light of lessons learned." JM 9-28.800.



STEPS OF A RISK ASSESSMENT

- Risk Management Process – What methodology has the company used to identify, analyze, and address the particular risks it faces? What information or metrics has the company collected and used to help detect the type of misconduct in question?
 - How have the information or metrics informed the company's compliance program?
- Risk-Tailored Resource Allocation – Does the company devote a disproportionate amount of time to policing low-risk areas instead of high-risk areas, such as questionable payments to third-party consultants, suspicious trading activity, or excessive discounts to resellers and distributors?
 - Does the company give greater scrutiny, as warranted, to high-risk transactions (for instance, a large-dollar contract with a government agency in a high-risk country) than more modest and routine hospitality and entertainment?
- Updates and Revisions – Is the risk assessment current and subject to periodic review? Is the periodic review limited to a "snapshot" in time or based upon continuous access to operational data and information across functions? Has the periodic review led to updates in policies, procedures, and controls?
 - Do these updates account for risks discovered through misconduct or other problems with the compliance program?
- Lessons Learned – Does the company have a process for tracking and incorporating into its periodic risk assessment lessons learned either from the company's own prior issues or from those of other companies operating in the same industry and/or geographical region



POLICIES AND PROCEDURES

Any well-designed compliance program entails policies and procedures that give both content and effect to ethical norms and that address and aim to reduce risks identified by the company as part of its risk assessment process.

As a threshold matter, prosecutors should examine whether the company has a code of conduct that sets forth, among other things, the company's commitment to full compliance with relevant Federal laws that is accessible and applicable to all company employees.

As a corollary, prosecutors should also assess whether the company has established policies and procedures that incorporate the culture of compliance into its day-to-day operations.

- Design – What is the company's process for designing and implementing new policies and procedures and updating existing policies and procedures, and has that process changed over time? Who has been involved in the design of policies and procedures?
 - Have business units been consulted prior to rolling them out?
- Comprehensiveness – What efforts has the company made to monitor and implement policies and procedures that reflect and deal with the spectrum of risks it faces, including changes to the legal and regulatory landscape?
- Accessibility – How has the company communicated its policies and procedures to all employees and relevant third parties? If the company has foreign subsidiaries, are there linguistic or other barriers to foreign employees' access?
 - Have the policies and procedures been published in a searchable format for easy reference?
 - Does the company track access to various policies and procedures to understand what policies are attracting more attention from relevant employees?
- Responsibility for Operational Integration – Who has been responsible for integrating policies and procedures?
 - Have they been rolled out in a way that ensures employees' understanding of the policies? In what specific ways are compliance policies and procedures reinforced through the company's internal control systems?
- Gatekeepers – What, if any, guidance and training has been provided to key gatekeepers in the control processes (e.g., those with approval authority or certification responsibilities)?
 - Do they know what misconduct to look for? Do they know when and how to escalate concerns?



TRAINING AND COMMUNICATION

- Prosecutors should assess the steps taken by the company to ensure that policies and procedures have been integrated into the organization, including through periodic training and certification for all directors, officers, relevant employees, and, where appropriate, agents and business partners.
- Prosecutors should also assess whether the company has relayed information in a manner tailored to the audience's size, sophistication, or subject matter expertise.
 - Some companies, for instance, give employees practical advice or case studies to address real-life scenarios, and/or guidance on how to obtain ethics advice on a case-by-case basis as needs arise.
 - Other companies have invested in shorter, more targeted training sessions to enable employees to timely identify and raise issues to appropriate compliance, internal audit, or other risk management functions.
 - Prosecutors should also assess whether the training adequately covers prior compliance incidents and how the company measures the effectiveness of its training curriculum.



TRAINING AND COMMUNICATION CONTINUED

- Prosecutors, in short, should examine whether the compliance program is being disseminated to, and understood by, employees in practice in order to decide whether the compliance program is “truly effective.” JM 9-28.800.
 - Risk-Based Training – What training have employees in relevant control functions received?
 - Has the company provided tailored training for high-risk and control employees, including training that addresses risks in the area where the misconduct occurred?
 - Have supervisory employees received different or supplementary training?
 - What analysis has the company undertaken to determine who should be trained and on what subjects?
 - Form/Content/Effectiveness of Training – Has the training been offered in the form and language appropriate for the audience? Is the training provided online or in person (or both), and what is the company’s rationale for its choice?
 - Has the training addressed lessons learned from prior compliance incidents? Whether online or in person, is there a process by which employees can ask questions arising out of the trainings?
 - How has the company measured the effectiveness of the training?
 - Have employees been tested on what they have learned? How has the company address employees who fail all or a portion of the testing?
 - Has the company evaluated the extent to which the training has an impact on employee behavior or operations?
 - Communications about Misconduct – What has senior management done to let employees know the company’s position concerning misconduct?
 - What communications have there been generally when an employee is terminated or otherwise disciplined for failure to comply with the company’s policies, procedures, and controls (e.g., anonymized descriptions of the type of misconduct that leads to discipline)?
 - Availability of Guidance – What resources have been available to employees to provide guidance relating to compliance policies?
 - How has the company assessed whether its employees know when to seek advice and whether they would be willing to do so



CONFIDENTIAL REPORTING STRUCTURE AND INVESTIGATION PROCESS

- Prosecutors should assess whether the company’s complaint-handling process includes proactive measures to create a workplace atmosphere without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers.
- Prosecutors should also assess the company’s processes for handling investigations of such complaints, including the routing of complaints to proper personnel, timely completion of thorough investigations, and appropriate follow-up and discipline.
- Confidential reporting mechanisms are highly probative of whether a company has “established corporate governance mechanisms that can effectively detect and prevent misconduct.” JM 9-28.800; see also U.S.S.G. § 8B2.1(b)(5)(C) (an effectively working compliance program will have in place, and have publicized, “a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization’s employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation”)
 - Effectiveness of the Reporting Mechanism – Does the company have an anonymous reporting mechanism and, if not, why not?
 - How is the reporting mechanism publicized to the company’s employees and other third parties?
 - Has it been used? Does the company take measures to test whether employees are aware of the hotline and feel comfortable using it?
 - How has the company assessed the seriousness of the allegations it received? Has the compliance function had full access to reporting and investigative information?



CONFIDENTIAL REPORTING STRUCTURE AND INVESTIGATION PROCESS

- Properly Scoped Investigations by Qualified Personnel – How does the company determine which complaints or red flags merit further investigation?
 - How does the company ensure that investigations are properly scoped?
 - What steps does the company take to ensure investigations are independent, objective, appropriately conducted, and properly documented?
 - How does the company determine who should conduct an investigation, and who makes that determination?
- Investigation Response – Does the company apply timing metrics to ensure responsiveness?
 - Does the company have a process for monitoring the outcome of investigations and ensuring accountability for the response to any findings or recommendations?
- Resources and Tracking of Results – Are the reporting and investigating mechanisms sufficiently funded?
 - How has the company collected, tracked, analyzed, and used information from its reporting mechanisms?
 - Does the company periodically analyze the reports or investigation findings for patterns of misconduct or other red flags for compliance weaknesses?
 - Does the company periodically test the effectiveness of the hotline, for example by tracking a report from start to finish



THIRD PARTY MANAGEMENT

- Prosecutors should assess the extent to which the company has an understanding of the qualifications and associations of third-party partners, including the agents, consultants, and distributors that are commonly used to conceal misconduct, such as the payment of bribes to foreign officials in international business transactions.
- Prosecutors should also assess whether the company knows the business rationale for needing the third party in the transaction, and the risks posed by third-party partners, including the third-party partners' reputations and relationships, if any, with foreign officials.
 - For example, a prosecutor should analyze whether the company has ensured that contract terms with third parties specifically describe the services to be performed, that the third party is actually performing the work, and that its compensation is commensurate with the work being provided in that industry and geographical region.
- Prosecutors should further assess whether the company engaged in ongoing monitoring of the third-party relationships, be it through updated due diligence, training, audits, and/or annual compliance certifications by the third party.
- In sum, a company's third-party management practices are a factor that prosecutors should assess to determine whether a compliance program is in fact able to "detect the particular types of misconduct most likely to occur in a particular corporation's line of business." JM 9- 28.800.



THIRD PARTY MANAGEMENT CONTINUED

- Risk-Based and Integrated Processes – How has the company's third-party management process corresponded to the nature and level of the enterprise risk identified by the company?
 - How has this process been integrated into the relevant procurement and vendor management processes?
- Appropriate Controls – How does the company ensure there is an appropriate business rationale for the use of third parties? If third parties were involved in the underlying misconduct, what was the business rationale for using those third parties?
 - What mechanisms exist to ensure that the contract terms specifically describe the services to be performed, that the payment terms are appropriate, that the described contractual work is performed, and that compensation is commensurate with the services rendered?
- Management of Relationships – How has the company considered and analyzed the compensation and incentive structures for third parties against compliance risks?
 - How does the company monitor its third parties?
 - Does the company have audit rights to analyze the books and accounts of third parties, and has the company exercised those rights in the past?
 - How does the company train its third party relationship managers about compliance risks and how to manage them?
 - How does the company incentivize compliance and ethical behavior by third parties?
 - Does the company engage in risk management of third parties throughout the lifespan of the relationship, or primarily during the onboarding process?
- Real Actions and Consequences – Does the company track red flags that are identified from due diligence of third parties and how those red flags are addressed?
 - Does the company keep track of third parties that do not pass the company's due diligence or that are terminated, and does the company take steps to ensure that those third parties are not hired or re-hired at a later date?
 - If third parties were involved in the misconduct at issue in the investigation, were red flags identified from the due diligence or after hiring the third party, and how were they resolved?
 - Has a similar third party been suspended, terminated, or audited as a result of compliance issues?



MERGERS AND ACQUISITIONS (M&A)

- A well-designed compliance program should include comprehensive due diligence of any acquisition targets, as well as a process for timely and orderly integration of the acquired entity into existing compliance program structures and internal controls. Pre-M&A due diligence, where possible, enables the acquiring company to evaluate more accurately each target's value and negotiate for the costs of any corruption or misconduct to be borne by the target. Flawed or incomplete pre- or post-acquisition due diligence and integration can allow misconduct to continue at the target company, causing resulting harm to a business's profitability and reputation and risking civil and criminal liability.
- The extent to which a company subjects its acquisition targets to appropriate scrutiny is indicative of whether its compliance program is, as implemented, able to effectively enforce its internal controls and remediate misconduct at all levels of the organization.
 - Due Diligence Process – Was the company able to complete pre-acquisition due diligence and, if not, why not? Was the misconduct or the risk of misconduct identified during due diligence? Who conducted the risk review for the acquired/merged entities and how was it done? What is the M&A due diligence process generally?
 - Integration in the M&A Process – How has the compliance function been integrated into the merger, acquisition, and integration process?
 - Process Connecting Due Diligence to Implementation – What has been the company's process for tracking and remediating misconduct or misconduct risks identified during the due diligence process?
 - What has been the company's process for implementing compliance policies and procedures, and conducting post acquisition audits, at newly acquired entity.



IS THE CORPORATION'S COMPLIANCE PROGRAM ADEQUATELY RESOURCED AND EMPOWERED TO FUNCTION EFFECTIVELY?

- Even a well-designed compliance program may be unsuccessful in practice if implementation is lax, under-resourced, or otherwise ineffective. Prosecutors are instructed to probe specifically whether a compliance program is a “paper program” or one “implemented, reviewed, and revised, as appropriate, in an effective manner.” JM 9-28.800. In addition, prosecutors should determine “whether the corporation has provided for a staff sufficient to audit, document, analyze, and utilize the results of the corporation’s compliance efforts.” JM 9- 28.800. Prosecutors should also determine “whether the corporation’s employees are adequately informed about the compliance program and are convinced of the corporation’s commitment to it.” JM 9-28.800; see also JM 9-47.120(2)(c) (criteria for an effective compliance program include “[t]he company’s culture of compliance, including awareness among employees that any criminal conduct, including the conduct underlying the investigation, will not be tolerated”).
- A Commitment by Senior and Middle Management Beyond compliance structures, policies, and procedures, it is important for a company to create and foster a culture of ethics and compliance with the law at all levels of the company. The effectiveness of a compliance program requires a high-level commitment by company leadership to implement a culture of compliance from the middle and the top.



IS THE CORPORATION'S COMPLIANCE PROGRAM ADEQUATELY RESOURCED AND EMPOWERED TO FUNCTION EFFECTIVELY?

- The company’s top leaders – the board of directors and executives – set the tone for the rest of the company. Prosecutors should examine the extent to which senior management have clearly articulated the company’s ethical standards, conveyed and disseminated them in clear and unambiguous terms, and demonstrated rigorous adherence by example. Prosecutors should also examine how middle management, in turn, have reinforced those standards and encouraged employees to abide by them. See U.S.S.G. § 8B2.1(b)(2)(A)-(C) (the company’s “governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight” of it; “[h]igh-level personnel ... shall ensure that the organization has an effective compliance and ethics program” (emphasis added)).
 - Conduct at the Top – How have senior leaders, through their words and actions, encouraged or discouraged compliance, including the type of misconduct involved in the investigation? What concrete actions have they taken to demonstrate leadership in the company’s compliance and remediation efforts? How have they modelled proper behavior to subordinates? Have managers tolerated greater compliance risks in pursuit of new business or greater revenues? Have managers encouraged employees to act unethically to achieve a business objective, or impeded compliance personnel from effectively implementing their duties?
 - Shared Commitment – What actions have senior leaders and middle-management stakeholders (e.g., business and operational managers, finance, procurement, legal, human resources) taken to demonstrate their commitment to compliance or compliance personnel, including their remediation efforts? Have they persisted in that commitment in the face of competing interests or business objectives?
 - Oversight – What compliance expertise has been available on the board of directors? Have the board of directors and/or external auditors held executive or private sessions with the compliance and control functions? What types of information have the board of directors and senior management examined in their exercise of oversight in the area in which the misconduct occurred?



AUTONOMY AND RESOURCES

- Prosecutors should evaluate how the compliance program is structured. Additionally, prosecutors should address the sufficiency of the personnel and resources within the compliance function, in particular, whether those responsible for compliance have:
 - (1) sufficient seniority within the organization;
 - (2) sufficient resources, namely, staff to effectively undertake the requisite auditing, documentation, and analysis; and
 - (3) sufficient autonomy from management, such as direct access to the board of directors or the board's audit committee.
 - The sufficiency of each factor, however, will depend on the size, structure, and risk profile of the particular company. "A large organization generally shall devote more formal operations and greater resources . . . than shall a small organization." Commentary to U.S.S.G. § 8B2.1 note 2(C).
- By contrast, "a small organization may [rely on] less formality and fewer resources." *Id.* Regardless, if a compliance program is to be truly effective, compliance personnel must be empowered within the company.
- Prosecutors should evaluate whether "internal audit functions [are] conducted at a level sufficient to ensure their independence and accuracy," as an indicator of whether compliance personnel are in fact empowered and positioned to "effectively detect and prevent misconduct." JM 9-28.800. Prosecutors should also evaluate "[t]he resources the company has dedicated to compliance," "[t]he quality and experience of the personnel involved in compliance, such that they can understand and identify the transactions and activities that pose a potential risk," and "[t]he authority and independence of the compliance function and the availability of compliance expertise to the board." JM 9-47.120(2)(c); see also JM 9-28.800 (instructing prosecutors to evaluate whether "the directors established an information and reporting system in the organization reasonably designed to provide management and directors with timely and accurate information sufficient to allow them to reach an informed decision regarding the organization's compliance with the law"); U.S.S.G. § 8B2.1(b)(2)(C) (those with "day-to-day operational responsibility" shall have "adequate resources, appropriate authority and direct access to the governing authority or an appropriate subgroup of the governing authority").



AUTONOMY AND RESOURCES

- Structure – Where within the company is the compliance function housed (e.g., within the legal department, under a business function, or as an independent function reporting to the CEO and/or board)? To whom does the compliance function report? Is the compliance function run by a designated chief compliance officer, or another executive within the company, and does that person have other roles within the company? Are compliance personnel dedicated to compliance responsibilities, or do they have other, non-compliance responsibilities within the company? Why has the company chosen the compliance structure it has in place? What are the reasons for the structural choices the company has made?
- Seniority and Stature – How does the compliance function compare with other strategic functions in the company in terms of stature, compensation levels, rank/title, reporting line, resources, and access to key decision-makers? What has been the turnover rate for compliance and relevant control function personnel? What role has compliance played in the company's strategic and operational decisions? How has the company responded to specific instances where compliance raised concerns? Have there been transactions or deals that were stopped, modified, or further scrutinized as a result of compliance concerns?
- Experience and Qualifications – Do compliance and control personnel have the appropriate experience and qualifications for their roles and responsibilities? Has the level of experience and qualifications in these roles changed over time? How does the company invest in further training and development of the compliance and other control personnel? Who reviews the performance of the compliance function and what is the review process?
- Funding and Resources – Has there been sufficient staffing for compliance personnel to effectively audit, document, analyze, and act on the results of the compliance efforts? Has the company allocated sufficient funds for the same? Have there been times when requests for resources by compliance and control functions have been denied, and if so, on what grounds?
- Data Resources and Access – Do compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of policies, controls, and transactions? Do any impediments exist that limit access to relevant sources of data and, if so, what is the company doing to address the impediments?
- Autonomy – Do the compliance and relevant control functions have direct reporting lines to anyone on the board of directors and/or audit committee? How often do they meet with directors? Are members of the senior management present for these meetings? How does the company ensure the independence of the compliance and control personnel?
- Outsourced Compliance Functions – Has the company outsourced all or parts of its compliance functions to an external firm or consultant? If so, why, and who is responsible for overseeing or liaising with the external firm or consultant? What level of access does the external firm or consultant have to company information? How has the effectiveness of the outsourced process been assessed?



INCENTIVES AND DISCIPLINARY MEASURES

- Prosecutors should also assess the extent to which the company's communications convey to its employees that unethical conduct will not be tolerated and will bring swift consequences, regardless of the position or title of the employee who engages in the conduct. See U.S.S.G. § 8B2.1(b)(5)(C) ("the organization's compliance program shall be promoted and enforced consistently throughout the organization through
 - (A) appropriate incentives to perform in accordance with the compliance and ethics program; and
 - (B) appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct").
 - By way of example, some companies have found that publicizing disciplinary actions internally, where appropriate and possible, can have valuable deterrent effects. At the same time, some companies have also found that providing positive incentives – personnel promotions, rewards, and bonuses for improving and developing a compliance program or demonstrating ethical leadership – have driven compliance. Some companies have even made compliance a significant metric for management bonuses and/or have made working on compliance a means of career advancement.
- Human Resources Process – Who participates in making disciplinary decisions, including for the type of misconduct at issue? Is the same process followed for each instance of misconduct, and if not, why? Are the actual reasons for discipline communicated to employees? If not, why not? Are there legal or investigation-related reasons for restricting information, or have pre-textual reasons been provided to protect the company from whistleblowing or outside scrutiny?
- Consistent Application – Have disciplinary actions and incentives been fairly and consistently applied across the organization? Does the compliance function monitor its investigations and resulting discipline to ensure consistency? Are there similar instances of misconduct that were treated disparately, and if so, why?
- Incentive System – Has the company considered the implications of its incentives and rewards on compliance? How does the company incentivize compliance and ethical behavior? Have there been specific examples of actions taken (e.g., promotions or awards denied) as a result of compliance and ethics considerations? Who determines the compensation, including bonuses, as well as discipline and promotion of compliance personnel?



DOES THE CORPORATION'S COMPLIANCE PROGRAM WORK IN PRACTICE?

- The Principles of Federal Prosecution of Business Organizations require prosecutors to assess "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision." JM 9-28.300.
 - Due to the backward-looking nature of the first inquiry, one of the most difficult questions prosecutors must answer in evaluating a compliance program following misconduct is whether the program was working effectively at the time of the offense, especially where the misconduct was not immediately detected.
- In answering this question, it is important to note that the existence of misconduct does not, by itself, mean that a compliance program did not work or was ineffective at the time of the offense. See U.S.S.G. § 8B2.1(a) ("[T]he failure to prevent or detect the instant offense does not mean that the program is not generally effective in preventing and deterring misconduct").
 - Indeed, "[t]he Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees." JM 9-28.800. Of course, if a compliance program did effectively identify misconduct, including allowing for timely remediation and self-reporting, a prosecutor should view the occurrence as a strong indicator that the compliance program was working effectively.
- In assessing whether a company's compliance program was effective at the time of the misconduct, prosecutors should consider whether and how the misconduct was detected, what investigation resources were in place to investigate suspected misconduct, and the nature and thoroughness of the company's remedial efforts.
- To determine whether a company's compliance program is working effectively at the time of a charging decision or resolution, prosecutors should consider whether the program evolved over time to address existing and changing compliance risks.
 - Prosecutors should also consider whether the company undertook an adequate and honest root cause analysis to understand both what contributed to the misconduct and the degree of remediation needed to prevent similar events in the future.
- For example, prosecutors should consider, among other factors, "whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems" and "whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future."
 - Benczkowski Memo at 2 (observing that "[w]here a corporation's compliance program and controls are demonstrated to be effective and appropriately resourced at the time of resolution, a monitor will not likely be necessary").



CONTINUOUS IMPROVEMENT, PERIODIC TESTING AND REVIEW

- A company's business changes over time, as do the environments in which it operates, the nature of its customers, the laws that govern its actions, and the applicable industry standards.
- Prosecutors should consider whether the company has engaged in meaningful efforts to review its compliance program and ensure that it is not stale. Some companies survey employees to gauge the compliance culture and evaluate the strength of controls, and/or conduct periodic audits to ensure that controls are functioning well, though the nature and frequency of evaluations may depend on the company's size and complexity.
- Prosecutors may reward efforts to promote improvement and sustainability. In evaluating whether a particular compliance program works in practice, prosecutors should consider "revisions to corporate compliance programs in light of lessons learned." JM 9-28.800; see also JM 9-47-120(2)(c) (looking to "[t]he auditing of the compliance program to assure its effectiveness").
- Prosecutors should likewise look to whether a company has taken "reasonable steps" to "ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct," and "evaluate periodically the effectiveness of the organization's" program. U.S.S.G. § 8B2.1(b)(5). Proactive efforts like these may not only be rewarded in connection with the form of any resolution or prosecution (such as through remediation credit or a lower applicable fine range under the Sentencing Guidelines), but more importantly, may avert problems down the line.
 - Internal Audit – What is the process for determining where and how frequently internal audit will undertake an audit, and what is the rationale behind that process? How are audits carried out? What types of audits would have identified issues relevant to the misconduct? Did those audits occur and what were the findings? What types of relevant audit findings and remediation progress have been reported to management and the board on a regular basis? How have management and the board followed up? How often does internal audit conduct assessments in high-risk areas?
 - Control Testing – Has the company reviewed and audited its compliance program in the area relating to the misconduct? More generally, what testing of controls, collection and analysis of compliance data, and interviews of employees and third parties does the company undertake? How are the results reported and action items tracked?
 - Evolving Updates – How often has the company updated its risk assessments and reviewed its compliance policies, procedures, and practices? Has the company undertaken a gap analysis to determine if particular areas of risk are not sufficiently addressed in its policies, controls, or training? What steps has the company taken to determine whether policies/procedures/practices make sense for particular business segments/subsidiaries? Does the company review and adapt its compliance program based upon lessons learned from its own misconduct and/or that of other companies facing similar risks?
 - Culture of Compliance – How often and how does the company measure its culture of compliance? Does the company seek input from all levels of employees to determine whether they perceive senior and middle management's commitment to compliance? What steps has the company taken in response to its measurement of the compliance culture?



INVESTIGATION OF MISCONDUCT

- An effective investigations structure will also have an established means of documenting the company's response, including any disciplinary or remediation measures taken.
 - Properly Scoped Investigation by Qualified Personnel – How has the company ensured that the investigations have been properly scoped, and were independent, objective, appropriately conducted, and properly documented?
 - Response to Investigations – Have the company's investigations been used to identify root causes, system vulnerabilities, and accountability lapses, including among supervisory managers and senior executives? What has been the process for responding to investigative findings? How high up in the company do investigative findings



ANALYSIS AND REMEDIATION OF ANY UNDERLYING MISCONDUCT

- Prosecutors evaluating the effectiveness of a compliance program are instructed to reflect back on “the extent and pervasiveness of the criminal misconduct; the number and level of the corporate employees involved; the seriousness, duration, and frequency of the misconduct; and any remedial actions taken by the corporation, including, for example, disciplinary action against past violators uncovered by the prior compliance program, and revisions to corporate compliance programs in light of lessons learned.” JM 9-28.800; see also JM 9-47.120(3)(c) (“to receive full credit for timely and appropriate remediation” under the FCPA Corporate Enforcement Policy, a company should demonstrate “a root cause analysis” and, where appropriate, “remediation to address the root causes”).
- Prosecutors should consider “any remedial actions taken by the corporation, including, for example, disciplinary action against past violators uncovered by the prior compliance program.” JM 98-28.800; see also JM 9-47-120(2)(c) (looking to “[a]ppropriate discipline of employees, including those identified by the company as responsible for the misconduct, either through direct participation or failure in oversight, as well as those with supervisory authority over the area in which the criminal conduct occurred” and “any additional steps that demonstrate recognition of the seriousness of the misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition of such misconduct, including measures to identify future risk”).
 - Root Cause Analysis – What is the company’s root cause analysis of the misconduct at issue? Were any systemic issues identified? Who in the company was involved in making the analysis?
 - Prior Weaknesses – What controls failed? If policies or procedures should have prohibited the misconduct, were they effectively implemented, and have functions that had ownership of these policies and procedures been held accountable?
 - Payment Systems – How was the misconduct in question funded (e.g., purchase orders, employee reimbursements, discounts, petty cash)? What processes could have prevented or detected improper access to these funds? Have those processes been improved?
 - Vendor Management – If vendors were involved in the misconduct, what was the process for vendor selection and did the vendor undergo that process?
 - Prior Indications – Were there prior opportunities to detect the misconduct in question, such as audit reports identifying relevant control failures or allegations, complaints, or investigations? What is the company’s analysis of why such opportunities were missed?
 - Remediation – What specific changes has the company made to reduce the risk that the same or similar issues will not occur in the future? What specific remediation has addressed the issues identified in the root cause and missed opportunity analysis?
 - Accountability – What disciplinary actions did the company take in response to the misconduct and were they timely? Were managers held accountable for misconduct that occurred under their supervision? Did the company consider disciplinary actions for failures in supervision? What is the company’s record (e.g., number and types of disciplinary actions) on employee discipline relating to the types of conduct at issue? Has the company ever terminated or otherwise disciplined anyone (reduced or eliminated bonuses, issued a warning letter, etc.) for the type of misconduct at issue.



CITED SOURCES

- Justice Manual (“JM”) 9-28.000 Principles of Federal Prosecution of Business Organizations, Justice Manual, available at <https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations>.
- JM 9-47.120 FCPA Corporate Enforcement Policy, available at <https://www.justice.gov/jm/jm-9-47000-foreign-corrupt-practices-act-1977#9-47.120>.
- Chapter 8 – Sentencing of Organizations - United States Sentencing Guidelines (“U.S.S.G.”), available at <https://www.ussc.gov/guidelines/2018-guidelinesmanual/2018-chapter-8#N>.
- Memorandum entitled “Selection of Monitors in Criminal Division Matters,” issued by Assistant Attorney General Brian Benczkowski on October 11, 2018, available at <https://www.justice.gov/criminal-fraud/file/1100366/download>.
- Criminal Division corporate resolution agreements, available at <https://www.justice.gov/news> (the Department of Justice’s (“DOJ”) Public Affairs website contains press releases for all Criminal Division corporate resolutions which contain links to charging documents and agreements).
- A Resource Guide to the U.S. Foreign Corrupt Practices Act (“FCPA Guide”), published in November 2012 and updated July 2020 by the DOJ and the Securities and Exchange Commission (“SEC”), available at <https://www.justice.gov/criminal-fraud/fcpa-resource-guide>.
- Good Practice Guidance on Internal Controls, Ethics, and Compliance, adopted by the Organization for Economic Co-operation and Development (“OECD”) Council on February 18, 2010, available at <https://www.oecd.org/daf/anti-bribery/44884389.pdf>.
- Anti-Corruption Ethics and Compliance Handbook for Business (“OECD Handbook”), published in 2013 by OECD, United Nations Office on Drugs and Crime, and the World Bank, available at <https://www.oecd.org/corruption/Anti-CorruptionEthicsComplianceHandbook.pdf>.
- Evaluation of Corporate Compliance Programs in Criminal Antitrust Investigations, published in July 2019 by DOJ’s Antitrust Division, available at <https://www.justice.gov/atr/page/file/1182001/download>.
- A Framework for OFAC Compliance Commitments, published in May 2019 by the Department of the Treasury’s Office of Foreign Assets Control (“OFAC”), available at https://www.treasury.gov/resource-center/sanctions/Documents/framework_ofac_cc.pdf.



GAP ANALYSIS

- A compliance program gap analysis is primarily a desk review that follows a checklist tied to the eight elements of a compliance program.
- Compliance programs must take inventory and audit the status of the program.
- It is a very limited project that consists of:
 - conducting a document review of charters,
 - the Code of Conduct,
 - compliance-related policies,
 - the hotline log,
 - minutes of compliance oversight committees,
 - the compliance training program, and
 - compliance audit plans, and reports.
- The review should provide milestones in addition to needs that strengthen the program.
- Observations and recommendations provide insight into the completeness and clarity of the documents, NOT the effectiveness of the elements in the operation of the compliance program.
- Don't just settle on the desk audit, go the distance and examine the operations to ensure it works in practice.



PROGRAM EFFECTIVENESS EVALUATION

- The compliance program effectiveness should focus on the elements of the program that are working and based on meeting the goals set out.
- Document analysis is a small part of the evaluation and goes beyond the desk audit.
- This process involves a more critical examination of the content of the written policies and procedures.
- Effectiveness Evaluations typically include but are not limited to:
 - Review of operations;
 - hotline and management of complaints;
 - interviews with key members of the executive team, Board, managers, and selected staff;
 - review of written guidance and whether it is achieving desired outcomes;
 - testing for credentialing and exclusion screening of staff and vendors;
 - Review of education and training programs;
 - monitoring of high risk areas; and
 - Review of the ongoing auditing processes to validate the effectiveness of the program.



HOW DOES AUDITING IMPACT COMPLIANCE

- **What we learn from our audits should translate into compliance...**
 - Policies and Procedures are derived from audits or in theory should be
 - If we use out of the box P&Ps without modification are we really compliant?
 - If we are not updating our P&Ps based on our audit findings do we have P&Ps?
- **As a result of audit findings, providers as always can expect to see increased efforts by the federal government to prevent, identify, and punish healthcare fraud.**

CMS' action plan:

- Increased number of prepayment reviews
- Increased post-payment reviews of medical necessity and medical record documentation supporting claims
- Overpayment recovery
- Providers identified by the audit as submitting improper claims will be targeted for more extensive investigation
- Increased review of evaluation and management claims (2010 study shows that more than 55% of levels selected were incorrect.)
- Demand for more documentation from providers who submit claims
- Increased security measures to prevent submission of claims from improper providers



MONITORING AND AUDITING

- The organization must evaluate the effectiveness of its compliance program on an ongoing basis by monitoring compliance with its standards and procedures and by reviewing its standards and procedures to ensure they are current and complete.
- A review of pending claims not yet submitted can establish a benchmark that will be used in ongoing reviews to chart the success of the organization's compliance efforts. (Counsel often recommend this be conducted under attorney-client privilege).



AUDITING, MONITORING & TRENDING

- Sentencing Guidelines & USSC Advisory Committee Recommendations
 - Two components: (1) Traditional Auditing and Monitoring to review/assess adherence to applicable laws, regulations and policies, and (2) Periodic evaluation of the effectiveness of the compliance program itself.
 - Auditing and Monitoring efforts should be tied to (driven by) results of the risk assessment process. Activities with greatest risk should normally be highest audit priority.



REGULATORY GUIDANCE

- **§8B2.1. Effective Compliance and Ethics Program**
- (a) To have an effective compliance and ethics program, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (b)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall—
 - (1) exercise due diligence to prevent and detect criminal conduct; and
 - (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.
- Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.
- (b) Due diligence and the promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the law within the meaning of subsection (a) minimally require the following:
 - (1) The organization shall establish standards and procedures to prevent and detect criminal conduct.



REGULATORY GUIDANCE CONTINUED

- (2) (A) The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.
- (B) High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program, as described in this guideline. Specific individual(s) within high-level personnel shall be assigned overall responsibility for the compliance and ethics program.
- (C) Specific individual(s) within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program. Individual(s) with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. To carry out such operational responsibility, such individual(s) shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.
- (3) The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program.
- (4) (A) The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subparagraph (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.

<http://www.ussc.gov/guidelines/2015-guidelines-manual/2015-chapter-8>



REGULATORY GUIDANCE

- **CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE:** *A Resource for Health Care Boards of Directors*

Structural Questions:

1. Does the compliance program address the significant risks of the organization?
2. How were those risks determined and how are new compliance risks identified and incorporated into the program?

Health care organizations operate in a highly regulated industry and must address various standards, government program conditions of participation and reimbursement, and other standards applicable to corporate citizens irrespective of industry. A comprehensive ongoing process of compliance risk assessment is important to the Board's awareness of new challenges to the organization and its evaluation of management's priorities and program resource allocation.

<http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRscceGuide.pdf>



DEVELOPING A CORRECTIVE ACTION PLAN

Corrective Action Plans (CAPS) are a critical component to sending a clear message that we are committed to doing the right thing. It shows our compliance plan is a living breathing document that's ever adjusting and growing with the organization.

Most compliance professionals want to self-disclose when an error is identified but self-disclosure is not always warranted. Oftentimes, things we make mistakes on don't lead to undeserved remunerations. They could simply be a breakdown in process that needs to be better defined or clarified.

- Before a decision is made about self-disclosure you should speak with your health care attorney to determine the best course of action... however, regardless of what the final determination is; you still need to develop a CAP.
- There are (5) basic aspects of a CAP:
 1. Issue/ Problem Definition- Identify the potential problem and provide a lay explanation of the problem (e.g. Cloning)
 2. Root Cause- Identify what led to the potential problem (e.g. The ease of cutting and pasting or carry forward within an EMR)
 3. Action Steps- Identify the steps taken to correct or reverse the potential problem (e.g. Training and Education for all providers documenting within the EMR)
 4. Improvement Benchmark(s) and Timeframes- How you will monitor the situation going forward to ensure compliance (e.g. Re-review of provider documentation within 30-days after training and education)
 5. Certification- The compliance officer or responsible party for ensuring compliance signs off on the CAP



Questions?

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