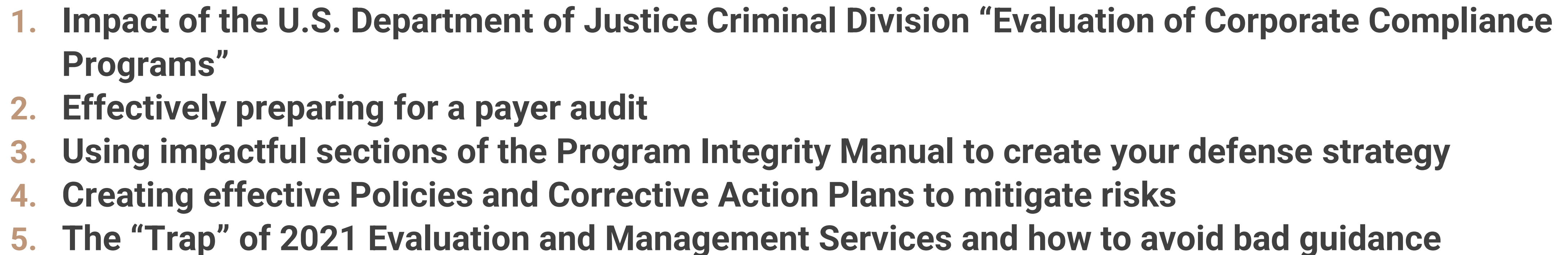
DISCLAIMER

- This PPT is accurate and complete as of the date of this presentation. Presenter bears 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 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.


1. Impact of the U.S. Department of Justice Criminal Division “Evaluation of Corporate Compliance Programs”
2. Effectively preparing for a payer audit
3. Using impactful sections of the Program Integrity Manual to create your defense strategy
4. Creating effective Policies and Corrective Action Plans to mitigate risks
5. The “Trap” of 2021 Evaluation and Management Services and how to avoid bad guidance

- “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?
  - 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 EDUCATION 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 s

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?
  - 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

- 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.

THIRD PARTY MANAGEMENT (CONTINUED)

- 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.
  - 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.
- 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

- 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") o JM 9-28.000 Principles of Federal Prosecution of Business Organizations, Justice Manual ("JM"), available at https://www.justice.gov/jm/jm-9-28000-principlesfederal-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 by the DOJ and the Securities and Exchange Commission ("SEC"), available at https://www.justice.gov/sites/default/files/criminalfraud/legacy/2015/01/16/guide.pdf.
- • 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/AntiCorruptionEthicsComplianceHandbook.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.
- 2 Prosecutors should consider whether certain aspects of a compliance program may be impacted by foreign law. Where a company asserts that it has structured its compliance program in a particular way or has made a compliance decision based on requirements of foreign law, prosecutors should ask the company the basis for the company's conclusion about foreign law, and how the company has addressed the issue to maintain the integrity and effectiveness of its compliance program while still abiding by foreign law. 3 As discussed in the Justice Manual, many companies operate in complex regulatory environments outside the normal experience of criminal prosecutors. JM 9-28.000. For example, financial institutions such as banks, subject to the Bank Secrecy Act statute and regulations, require prosecutors to conduct specialized analyses of their compliance programs in the context of their anti-money laundering requirements. Consultation with the Money Laundering and Asset Recovery Section is recommended when reviewing AML compliance. See https://www.justice.gov/criminal-mlars. Prosecutors may also wish to review guidance published by relevant federal and state agencies. See Federal Financial Institutions Examination Council/Bank Secrecy Act/Anti-Money Laundering Examination Manual, available at https://www.ffiec.gov/bsa aml infobase/pages manual/manual online.htm).

CULTIVATING AN ENVIRONMENT OF MISTRUST

- *"CMS and its contractors often cultivate an environment of mistrust and suspicion that all providers of certain services are inherently fraudulent. The sentiment is widely shared by anyone that has worked with CMS contractors in the area of program integrity and a similar environment is probable within the CMS Program Integrity Group. This type of environment leads investigators, contractors, and CMS to pursue providers in an aggressive manner, sometimes unfairly, based on little evidence or collaboration of any wrongdoing."*
- "It is not uncommon for a ZPIC to implement a 100% prepayment review of a provider's claims with no notification."
    - 2012 Whitepaper to Senate Finance Committee / van Halem Group

INTENTIONAL OR PLAIN IGNORANT

- "There is a lack of experience and training of ZPIC staff." In one specific case a member of management at a ZPIC was questioned regarding issues surrounding numerous errors being made by staff.
  - The ZPIC Manager said, "Not only was he aware of the errors being made but attributed them to issues related to workload, exhaustion, or lack or training."
- "Many ZPIC investigators lack sufficient training in coverage and reimbursement policies for the services under their review."
  - A provider contacted their local congressman to address concerns over incorrect denials in a ZPIC audit. The Congressman's office contacted CMS Central Office and submitted 11 examples of claims denied in error. The actual written response from CMS said they agreed that 7 of the 11 claims were in fact denied erroneously. However, the letter went on to state, "That regardless, the provider's error rate remained high so they will remain under investigation" despite the fact they had just received confirmation in the very same response that the error rate calculated was incorrect because of errors made by the contractor.
    - This not only supports a lack of training, but a lack of appropriate oversight and fairness."

- *Source: White paper Submission to Senate Finance Committee in response to Bipartisan Effort to Combat Waste, Fraud and Abuse in the Medicare and Medicaid Programs, June 29, 2012*

2015 OIG REPORT TO CMS

- "Often the ZPIC contractors have had no experience in the areas of fraud and abuse for which they should be accountable. The result is a loss to CMS of fraud and abuse funds and providers, many of which are small – medium sized businesses, are forced to spend thousands of dollars to address unfounded audits and investigations. This was evidenced when CMS lost $80 million of the $120 million paid to contractors in 2011, due to poor data when investigating fraud and abuse."
- According to the OIG report, "The significant lack of oversight of ZPIC contractors, who were awarded contracts averaging $81.9 million, is evidenced by the extreme and ill-founded actions taken by some ZPICs in unwarranted efforts to show CMS a return on investment.
- Contractors often employed significant, aggressive, and over-zealous audits, claims reviews and investigations against legitimate, not fraudulent, providers of healthcare services.
- The broad brush actions cost legitimate providers huge amounts of time, money and energy – inhibiting their ability to provide care to beneficiaries. Some are forced to leave Medicare, if not health care services all together.
- ZPICs are large and powerful corporations with the backing of the federal government. They apply heavy handed processes in a punitive manner to many legitimate providers over minor document infractions. Further exacerbating the problems are the individuals employed by CMS to oversee these contractors, who are often young and inexperienced and do not have healthcare or fraud investigation experience."

DEFINING COMPLIANCE

- Health care compliance is the process of following rules, regulations, and laws that relate to healthcare practices.
- Health care organizations are held to very strict standards, regulations, and laws from the federal and state levels and violating these can result in lawsuits, significant fines, loss of licenses and exclusion.
  - Here is what bothers me and should bother you - THE PAYERS ARE NOT HELD TO THE SAME STANDARDS!

THE FILIP MEMO

- The United States Attorneys' Manual ("USAM" now the Justice Manual) is a comprehensive collection of DOJ policies regarding civil and criminal enforcement issues. It includes specific policies concerning corporate prosecution guidelines.
  - Specifically, whether to criminally charge a corporation is governed by **JM 9-27.220 et seq**, which sets out what is referred to as the "Filip Factors," referring to former Deputy Attorney General Mark Filip;
  - In 2008, DOJ and then again in November 2018 revised its corporate prosecution guidelines in response to concerns that prosecutors were requiring companies to waive attorney-client privilege in order to earn cooperation credit;
  - Defense counsel who represent companies usually present facts and circumstances under the Filip Factors to support their argument for a specific resolution. Prosecutors are required to weigh all of the factors normally considered in the exercise of prosecutorial judgment: the sufficiency of the evidence; the likelihood of success at trial; the probable deterrent, rehabilitative and other consequences of conviction; and the adequacy of noncriminal approaches;
  - *When it comes to corporations, the USAM adds the Filip Factors to guide a decision on whether to bring charges, negotiate a plea or other agreement (i.e. deferred or non-prosecution agreement)*
- The emphasis on voluntary disclosure, enhancement of corporate compliance programs, and remediation underscore the importance that a company facing possible prosecution quickly assess the potential misconduct, decide whether to disclose and cooperate, initiate significant remediation efforts, and, most importantly, improve its corporate compliance program.

WHAT ARE THE FILIP FACTORS

- The Filip Factors include two specific factors focused on corporate compliance programs – one for the existence of a corporate compliance program at the time the wrongdoing occurred (number 5), and another focused on remedial actions taken by the company to enhance its compliance program in response to the misconduct (number 7)

1. the nature and seriousness of the offense, including the risk of harm to the public, and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime (*see* JM 9-28.400);
2. the pervasiveness of wrongdoing within the corporation, including the complicity in, or the condoning of, the wrongdoing by corporate management (*see* JM 9-28.500);
3. the corporation's history of similar misconduct, including prior criminal, civil, and regulatory enforcement actions against it (*see* JM 9-28.600);
4. the corporation's willingness to cooperate, including as to potential wrongdoing by its agents (*see* JM 9-28.700);
5. *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 (see JM 9-28.800)*;
6. the corporation's timely and voluntary disclosure of wrongdoing (*see* JM 9-28.900);
7. *the corporation's remedial actions, including, but not limited to, any efforts to implement an adequate and effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, or to pay restitution (see JM 9-28.1000)*;
8. collateral consequences, including whether there is disproportionate harm to shareholders, pension holders, employees, and others not proven personally culpable, as well as impact on the public arising from the prosecution (*see* JM 9-28.1100);
9. the adequacy of remedies such as civil or regulatory enforcement actions, including remedies resulting from the corporation's cooperation with relevant government agencies (*see* JM 9-28.1200); and
10. the adequacy of the prosecution of individuals responsible for the corporation's malfeasance (*see* JM 9-28.1300)."

  - ** "The factors listed in this section are intended to be illustrative of those that should be evaluated and are not an exhaustive list of potentially relevant considerations. Some of these factors may not apply to specific cases, and in some cases one factor may override all others. For example, the nature and seriousness of the offense may be such as to warrant prosecution regardless of the other factors. In most cases, however, no single factor will be dispositive. In addition, national law enforcement policies in various enforcement areas may require that more or less weight be given to certain of these factors than to others. Of course, prosecutors must exercise their thoughtful and pragmatic judgment in applying and balancing these factors, so as to achieve a fair and just outcome and promote respect for the law." [updated November 2018]*

SEAN'S TRUTH ABOUT "MEDICAL NECESSITY"

- Payers and enforcement agencies are watching. Enforcement actions and application of penalties have and will continue to increase, and programs like bundled payments and accountable care will be judged by adherence to "Medical Necessity" and avoidance of unnecessary care.
- Physician leadership is and will be more critical! Their role and scope within their organizations will become more complicated, clinical-data dependent and at times adversarial with their peers over what is clinically appropriate.
- "Medical Necessity" is a complex term and its application is not a straightforward set of operating policies and procedures or business processes. This is more than just a political talking point and someone giving a stump speech. Big Brother and his friends are paying close attention and their moves are more calculated because expectations are higher, rewards for recoveries are greater and penalties are stiffer.
- Responding appropriately requires critical, outside the box thinking! Turning a deaf ear or blind eye is just the opposite of what is needed. Practices must be diligent in their efforts to ferret out Fraud, Waste and Abuse!
- **That's the truth about "Medical Necessity"!**

UNDERSTANDING HOW TO DEFEND "MEDICAL NECESSITY"

- Unless the contrary is specified, the term "Medical Necessity" must refer to what is medically necessary for a particular patient, and hence entails an individual assessment rather than a general determination of what works in the ordinary case.
  - Second Circuit Court of Appeals, cited in Kaminski, Defining Medical Necessity,

http://www.cga.ct.gov/2007/rpt/2007-r-0055.htm

DEFINING "MEDICAL NECESSITY"

"Medically Necessary" or "Medical Necessity" shall mean health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: a) in accordance with **generally accepted standards of medical practice**; b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and c) not primarily for the convenience of the patient, physician or other health care provider, **and not more costly than an alternative service or sequence of services** at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.

MEDICARE'S VIEW OF "MEDICAL NECESSITY"

- In the Medicare program, "Medical Necessity" is defined under Title XVIII of the Social Security Act, Section 1862 (a) (1) (a): "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

The above is a legal doctrine by which evidence-based clinical standards are used to determine whether a treatment or procedure is reasonable, necessary and/or appropriate.

MEDICAL NECESSITY AND THE FALSE CLAIMS ACT

- The False Claims Act (FCA)
  - "Knowingly" the submission of false claims for the purpose of receiving an entitlement for non-covered services
  - Reverse False Claims
    - Knowing and improper avoidance of an obligation to pay monies to the U.S. Government
    - Affordable Care Act created statutory obligations to report and refund overpayments – 60 day rule / self-disclosure protocol
  - It is critical to understand the FCA covers potential false claims based on the conduct at the time the claims were submitted (affirmative false claims) as well as potential false claims based on later discovery and mishandling of overpayment refund obligations.

- The FCA Definition of Knowing
  - Actual knowledge, deliberate ignorance, or reckless disregard
  - Intent to defraud is no longer required, simply demonstrating claims were submitted with inaccurate information is all that is now required under the law.

THE FALSE CLAIMS ACT PENALTIES

"It is improper to bill Medicare for services or treatment that is not medically necessary. To knowingly do so is a violation of the False Claims Act…

A physician who knowingly bills for services which are not medically necessary can be prosecuted for fraud by the Office of Inspector General (OIG).

Violators face penalties between $11,000 and $22,000 for each service, an assessment of up to three (treble damages) times the amount billed, and exclusion from federal and state healthcare programs." –31 U.S. Code § 3729 – False claims (a)(1) (G)

THE FALSE CLAIMS ACT

- Under the FCA, a person is deemed to have acted "knowingly" when the person "acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b).
- As the Ninth Circuit has pointed out, the FCA knowledge standard does not extend to honest mistakes, but only to "lies." "Claims are not 'false' under the FCA unless they are furnished in violation of some controlling rule, regulation or standard". *See, e.g., United States ex rel. Local 342 v. Caputo Co.,* 321 F.3d 926, 933 (9th Cir.2003); *United States v. Southland Mgmt. Corp.,* 326 F.3d 669, 674-75 (5th Cir.2003) ("[W]hether a claim is valid depends on the contract, regulation, or statute that supposedly warrants it.
- It is only those claims for money or property to which a Defendant is not entitled that are 'false' for purposes of the False Claims Act") (citation omitted) (en banc); *United States ex rel. Hochman v. Nackman,* 145 F.3d 1069, 1073-74 (9th Cir.1998) (no falsity when Defendants' acts conformed with Veteran Administration payment guidelines); *United States ex rel. Lindenthal v. Gen. Dynamics Corp.,* 61 F.3d 1402, 1412 (9th Cir.1995) (whistleblower's FCA claims for payment based on work that satisfied contractual obligations "could not have been 'false or fraudulent' within the meaning of the [False Claims Act]"); *United States ex rel. Glass v. Medtronic, Inc.,* 957 F.2d 605, 608 (8th Cir.1992) (a statement cannot be "false" or "fraudulent" under FCA when the statement is consistent with regulations governing program).
- *Additionally, a Defendant does not knowingly submit false claims when he follows Government instructions regarding the claims. See United States ex rel. Butler v. Hughes Helicopters, Inc., 71 F.3d 321 (9th Cir.1995); Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir.1992).*

THE FALSE CLAIMS ACT

- Additionally, claims are not "false" under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government. *See United States ex rel. Lamers v. City of Green Bay,* 168 F.3d 1013, 1018 (7th Cir.1999) (holding that "errors based simply on faulty calculations or flawed reasoning are not false under the FCA . . . [a]nd imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA") (citations omitted); *Hagood v. Sonoma County Water Agency,* 81 F.3d 1465, 1477 (9th Cir.1996) ("How precise and how current the cost allocation needed to be in light of the [Water Supply Act's] imprecise and discretionary language was a disputed question within the [Government]. Even viewing [plaintiff's] evidence in the most favorable light, that evidence shows only a disputed legal issue; that is not enough to support a reasonable inference that the allocation was *false* within the meaning of the False Claims Act").

WHO'S REVIEWING YOUR CLAIMS…

Section 3.1.1.1

- The MACs, CERT, and ZPIC/UPICs/UPICs shall ensure that *medical record reviews for the purpose of making coverage determinations are performed by licensed nurses (RNs and LPNs) or physicians*, unless this task is delegated to other licensed health care professionals. RACs and the SMRC shall ensure that the credentials of their reviewers are consistent with the requirements in their respective SOWs. During a medical record review, nurse and physician reviewers may call upon other health care professionals (e.g. dieticians or physician specialists) for advice. The MACs, CERT, and ZPICs/UPICs shall ensure that services reviewed by other licensed health care professionals are within their scope of practice and that their MR strategy supports the need for their specialized expertise in the adjudication of particular claim type (i.e. speech therapy claim, physical therapy). RACs and the SMRC shall follow guidance related to calling upon other healthcare professionals as outlined in their respective SOWs. RACs shall ensure that a licensed medical professional will perform medical record reviews for the purpose of determining medical necessity, using their clinical review judgment to evaluate medical record documentation. *Certified coders will perform coding determinations. CERT and MACs are encouraged to make coding determinations by using certified coders. ZPIC/UPICs/UPICs have the discretion to make coding determinations using certified coders.*

Credential Files

- *The MACs, CERT, RACs, and ZPIC/UPICs shall maintain a credentials file for each reviewer (including consultants, contract staff, subcontractors, and temporary staff) who performs medical record reviews. The credentials file shall contain at least a copy of the reviewer's active professional license.*

Medicare Program Integrity Manual Chapter 3 – Verifying Potential Errors and Taking Corrective Action Section 3.3.1.1 - Medical Record Review (Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

DETERMINING MEDICAL NECESSITY

Clinical Review Judgment

- Clinical review judgment involves two steps:
  - The synthesis of all submitted medical record information (e.g. progress notes, diagnostic findings, medications, nursing notes, etc.) to create a longitudinal clinical picture of the patient and,
  - The application of this clinical picture to the review criteria is to make a reviewer determination on whether the clinical requirements in the relevant policy have been met. MAC, CERT, RAC, and ZPIC/UPIC clinical review staff shall use clinical review judgment when making medical record review determinations about a claim.

MEDICAL NECESSITY PER CMS

- Medicare excludes coverage for services not reasonable and necessary
  - "No payment may be made… for any expenses incurred for items or services which… are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42U.S.C. § 1395y(a)(1).
- Limitation/waiver of liability provides coverage if provider
  - "did not know, and could not reasonably have been expected to know," that payment would not be made due to the reasonable and necessary exclusion. 42 U.S.C. § 1395pp.
    - **Many fail to recognize that the CMS 1500 form contains a certification of medical necessity**

HERE'S WHERE THINGS GET TRICKY

- CMS Defines Medical Necessity How?
  - There are no actual regulatory provisions
  - CMS issues from time to time NCDs
  - LCDs may be issued by MACs
  - Medical Necessity is evaluated on a case-by-case basis by MACs which then opens the door to subjectivity and interpretation as to what potentially benefits the payer

CLEAR AND BINDING MEDICAL NECESSITY STANDARD

- The Medicare statute requires that any "rule" requirement, or other statement of policy (other than a material coverage decision) that establishes or changes a substantive legal standard" must be promulgated by regulation. 42 U.S.C § 1395hh.
  - Has CMS promulgated a standard for determining whether a service is reasonable and necessary?
  - Courts FROM TIME TO TIME give deference to the determination of the "Treating physician" (United States v. Prabhu, 442 F. Supp 2d 1008 (D. Nev 2006)
- Clarity of Medical Necessity issues affect whether a claim is "False and whether the requisite "knowledge" exists.
  - "Claims are not 'false' under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government." *Prabhu*
  - "a Defendant does not 'knowingly' submit a 'false' claim when his conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance." *Prabhu*

WHO DETERMINES WHAT IS "MEDICALLY NECESSARY"

A. **Treating Physicians -- The first section of the Medicare statute is the prohibition "Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."**

- From this, one could conclude that the beneficiary's physician should decide what services are medically necessary for the beneficiary, and a substantial line of authority in the Social Security disability benefits area holds that the treating physician's opinion is entitled to special weight and is binding upon the Secretary when not contradicted by substantial evidence.
- Some courts have applied the rationale of the "treating physician" rule in Medicare cases, and have rejected the Secretary's assertion that the treating physician rule should not be applied to Medicare determinations.

- **In *Holland vs. Sullivan*, the court concluded:**
  - Though the considerations bearing on the weight to be accorded a treating physician's opinion are not necessarily identical in the disability and Medicare context, **we would expect the Secretary to place significant reliance on the informed opinion of a treating physician** and either to **apply the treating physician rule**, with its component of "some extra weight" to be accorded that opinion, [even if contradicted by substantial evidence], or to supply a reasoned basis, in conformity with statutory purposes, for declining to do so.

HOW DO WE DEFEND MEDICAL NECESSITY

- Documentation within the Medical Record:
  - **Does "Medical Necessity" exist or likely exist but the issue is lacking documentation in the medical record?**
    - Physicians have a responsibility to provide sufficient documentation that paints a clear picture of each and encounter;
    - Determining whether the procedures in question are truly clinically necessary or if the issue is documentation related is critical to the defense of the investigation;
    - Make sure that all relevant medical records have been retrieved and reviewed. This means office notes, hospital notes, nursing home, rehabilitation, etc.;
    - Do LCDs or NCDs exist to provide documentation requirements;
    - If the allegations are that documentation is inaccurate, have we generated clinical rebuttals to further clarify the need for services and state the physicians opinion clearly.

STATISTICAL SAMPLING

Section 8.4.2 of the CMS Program Integrity Manual states the following:

- "If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made."
- While the above statement is specific to CMS and other government audits, it is also generally accepted amongst the statistical community. Accordingly, these criteria must be met for an extrapolation to take place.
- Because the accuracy and applicability of an extrapolation is so heavily dependent upon the statistical validity of the sample, *the first and perhaps the most important question to be answered is whether the sample is, in fact, statistically valid.*
- In many cases, a sample is assumed valid if there is a belief that the sample units were drawn randomly from the sampling frame or universe. *The term 'random' is most often defined here as each audit unit of interest (beneficiary, claim, claim line, etc.) has an equal and non-zero chance of being selected.* There is, however, an important difference between a sample being random and a sample being representative of the sampling frame from which it was drawn.
- According the 8.4.1.3 of the PIM, "The major steps in conducting statistical sampling are:
  - Selecting the provider or supplier;
  - Selecting the period to be reviewed;
  - Defining the universe, the sampling unit, and the sampling frame;
  - Designing the sampling plan and selecting the sample;
  - Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable,
  - Estimating the overpayment. Where an overpayment has been determined to exist, follow applicable instructions for notification and collection of the overpayment."

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. <u>Effective Compliance and Ethics Program</u>**
- (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 CONTINUED

- CORPORATE RESPONSIBILITYAND 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/040203CorpRespRsceGuide.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.

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- 1. Issue/ Problem Definition- Identify the potential problem and provide a lay explanation of the problem (e.g. Cloning)
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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

Policy on Risk Based Internal Auditing

Created:

Updated:

General:

The practice subscribes to a Risk Based Internal Audit Model as opposed to a compliance only model to ensure the organization's tolerance to risk (Risk Aversion) is fully understood and complied with by all employees regardless of position…

The organization relies on a six step process referred to as risk assessment matrix (RAM) to effectively and efficiently manage their compliance program.

Purpose:

A Risk based internal audit is critical since you cannot measure compliance with regulations, statutes and guidelines without assessing risk. Risk based Internal Audit (RBIA) is an internal methodology, which is primarily focused on the inherent risk involved in the activities or system and provide assurance that risk is being managed by the management within the defined risk appetite level. It is the risk management framework of the management team and seeks at every stage to reinforce the responsibility of management and Board of Directors for managing risk.

Risk based internal audits are conducted by the internal audit department or external vendor(s) to help the risk management function of the company by providing assurance about the risk mitigation.

Risk based internal audit allows for internal audit to provide assurance to the board that risk management processes are managing risks effectively, in relation to the risk appetite.

In Risk based internal auditing two types of risks are considered:

- Inherent Risk - Risk that is existed in the absence of any action or control or modification the event.
- Residual Risk - Risk that remains after controls are implemented or we can say residual of inherent risk.

Risk Assessment, allows the organization to understand the possibility and impact of a risk event and uses two (2) prospective:

- Likelihood: Probability of risk event (P)
- Consequences: Impact of risk event (I)

Policy:

The six-step RAM process covers the entire risk assessment process in a "closed-loop system"… This ensures the organization is completely aware of and prepared for the entire range of potential risks.

"MEDICAL NECESSITY" AND CHRONIC CONDITIONS

- "Of the nearly 55.5 million Medicare beneficiaries:
  - over three-quarters (78%) have at least one chronic condition which requires ongoing medical care and management;
  - Almost two-thirds (63%) have two or more chronic conditions, and;
  - Twenty percent of Medicare beneficiaries have five or more chronic conditions.
    - Thus, access to medical services that addresses the needs of people with chronic conditions is critical for the majority of Medicare beneficiaries."
      - *Medical Necessity Determinations in the Medicare Program- 2015*

THE AMA AND “MEDICAL NECESSITY”

- The AMA defines medical necessity as: “Healthcare services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other healthcare provider.”
  - “Statement of the American Medical Association to the Institute of Medicine’s Committee on Determination of Essential Health Benefits,” American Medical Association, January 14, 2011

ITEMS FOR CONSIDERATION IN PREPARING YOUR AUDIT APPEAL DEFENSE

- Provider Without Fault
- Waiver of Liability
- Treating Physician's Rule
- Challenges to Statistics
- Reopening Regulations

PROVIDER WITHOUT FAULT

- Section 1870 of the Social Security Act
- Once an overpayment is identified, payment will be made to a provider if the provider was without "fault " with regard to billing for and accepting payment for disputed services.

WAIVER OF LIABILITY

- Section 1879(a) of the Social Security Act
- Under waiver of liability, even if a service is determined to be not reasonable and necessary, payment may be rendered if the provider or supplier did not know, and could not reasonably have been expected to know, that payment would not be made.

- The treating physician rule, reflects that the determination that a service is "Medically Necessary" is binding and entitled to some extra weight, even if contradicted by substantial evidence, because the physician is inherently more familiar with the patient's medical condition than a retrospective reviewer

PROVIDER WITHOUT FAULT / TREATING PHYSICIAN RULE

- 42 C.F.R. § 482.30: Conditions of Participation: Utilization Review
- Provider should always argue that the opinion of the treating physician is the best evidence
  - There are no similar rulings from CMS with respect to Part B

CHALLENGES TO STATISTICAL SAMPLING

- Section 935 of the MMS
- The guidelines for conducting statistical extrapolations are set forth in the Medicare Program Integrity Manual (CMS Pub. 100-08), Chapter 3 §§ 3.10.1 through 3.10.11.2

STATISTICAL SAMPLING CONT'D

- In simple terms, we want the sample to be representative of the universe or, more colloquially, to "look like" the universe with regard to its characteristics. These characteristics might include what was paid for the procedure, coding characteristics, such as the differences between the vast array of procedure and service codes included in the HCPCS II coding universe. It may also have to do with specific characteristics found amongst the beneficiaries, which often more accurately define the types of diagnoses and treatments represented within the medical records.
- Some characteristics, such as charge, or paid amounts can be visualized by graphing data using histograms, for example. Non-valued characteristics, such as those subject to rules, regulations or guidelines, are more difficult to visualize in this way. For value-based characteristics, distribution and variance are two effective ways to look at representativeness of a sample to the universe (or sampling frame).
- Since I understand how insurance companies work, when they fail at establishing "Good Cause" they tend to revert back to Fraud, Waste or Abuse, which means they would be accusing your client of potentially violating the False Claims Act.
- Head them off at the pass. Under the FCA, a person is deemed to have acted "knowingly" when the person "acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). Pub 100-08 Medicare Program Integrity

Medicare Program Integrity Manual, Chapter 8, section 8.4.1.3 – *Steps for Conducting Statistical Sampling* (Rev. 377, 05-27-11)

THE ALJ PROCESS

- You can pretty much forget about success at the Redetermination or Reconsideration levels of appeal with Medicare.
  - The number of requests for an ALJ hearing or review increased 1,222 percent, from fiscal year (FY) 2009 through FY 2014.
  - Despite significant gains in OMHA ALJ productivity (in FY 2014, each OMHA ALJ issued, on average, a record 1,048 decisions and an additional 456 dismissals),
  - the number of requests for an ALJ hearing and requests for reviews of QIC and IRE dismissals continue to exceed OMHA's capacity to adjudicate the requests.
  - As of April 30, 2016, OMHA had over 750,000 pending appeals, while OMHA's adjudication capacity was 77,000 appeals per year, with an additional adjudication capacity of 15,000 appeals per year expected by the end of Fiscal Year 2017
    - This is a 10 year backlog… the same as in India…
      - ***The statutory changes made by BIPA include a 90-day adjudication time frame for ALJs to adjudicate appeals of QIC reconsideration beginning on the date that a request for an ALJ hearing is timely filed.***

SAMPLE SIZE

- Probe Audits- Arcane and unreliable method to perform an audit.
  - 30 is the number most often used by ZPIC and RAC auditors.
  - OIG normally recommends 100 when engaging in self-disclosure audits
  - Either of these samples can be used for extrapolation. So, if you are performing one of these audits use a number lower than 30 and don't create a statistically valid random sample
  - Consider conducting internal audits under attorney/client privilege
- Educational Audits – 5-10 encounters
- Statistically valid audits – This depends on whether or not there is going to be an extrapolation. Typically you would want to see 30 encounters per CPT code in question according to The OIG.
- Baseline Audit- 10% selection of the provider's patient universe.
  - Performance of the audits prospectively vs retrospectively is a preference but both could result in expansion of the audit sample size, lead to refunds and/or self-disclosure.

- Identifies over time the practice’s progress in reducing or eliminating potential areas of vulnerability
- This process known as *benchmarking* allows the practice to chart its compliance efforts by showing a reduction or increase in the number of claims paid and denied
- The process is used to examine the claim development and submission process from patient intake through claim submission and payment
- This process provides identification of elements within this process which may contribute to non-compliance or that may need to be the focus for improving execution

ERRONEOUS VS. FRAUDULENT

- Erroneous- claims submitted to the carriers with inadvertence or negligence. Refunds should be made once a detection is made. Providers are not subject to civil penalties, interest or jail
- Fraudulent- claims submitted intentionally or with reckless disregard for the intent of inappropriate monetary gain. Providers are subject to civil penalties and jail

COMPLIANCE MONITORING

- The OIG acknowledges that full implementation of all components may not be feasible for all practices
- Practices should adopt those components which are likely to provide an identifiable benefit based on previous history of specific billing problems or compliance issues
  - Auditing and monitoring of the plan must be one of the seven steps adopted
- It is advised that providers participate in other compliance programs, such as the hospitals or other settings in which the physician practices

AUDITING AND MONITORING IMPLEMENTATION

- This step is crucial to the success of a compliance program
- This process not only ensures the practice's standards and procedures are current, but also whether they are accurate and if the compliance program is working
  - ensuring individuals are carrying out their responsibilities

- What Regulatory Guidance Exists
- Building The Team and Taking Accountability
- Risk Identification and Mitigation
- Assessing and Documenting
- Prioritizing and Reporting
- Ongoing Monitoring to Identify New Risks

- On September 9, 2015, the Department of Justice ("DOJ") issued new guidance on individual accountability for corporate wrongdoing.
- In the memorandum and an accompanying speech by the Deputy Attorney General Sally Q. Yates, the DOJ announced a new initiative designed to combat corporate misconduct and seek accountability from individuals involved in suspected corporate wrongdoing.
- While the Yates memorandum provides six specific criteria designed to guide prospective DOJ enforcement, largely against "C suite" individuals, it offers several significant takeaways and may call for a shift in how companies and their directors carry out their compliance and internal investigation functions.

KEY ELEMENTS OF THE YATES MEMORANDUM

- To be eligible for *any* cooperation credit, corporations must provide to the DOJ "all relevant facts" about the individuals involved in the corporate misconduct.
- *Both* criminal and civil corporate investigations should focus on individuals from the inception of the investigation.
- Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.
- Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
- Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires, and declinations as to individuals in such cases must be memorialized.
- Civil DOJ attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.

TAKEAWAYS FOR HEALTH CARE COMPANIES AND THEIR DIRECTORS AND COUNSEL

- ***Cooperation is "all or nothing"— companies cannot receive cooperation credit without identifying culpable individuals and divulging all relevant facts.***
  - According to the Yates memorandum, companies can *only* receive cooperation credit in criminal or civil matters by "completely disclos[ing]" <u>*all* relevant facts about individual misconduct—regardless of an individual's position, status, or seniority in the company.</u>
  - With this new "all or nothing" approach, companies cannot receive partial credit for cooperation that stops short of identifying culpable individuals.
  - Companies will need to weigh carefully the benefits of this type of voluntary disclosure against the risk of not receiving credit, or that the information will be leveraged by the government in subsequent proceedings.

THE GUIDANCE MAY RESULT IN DE FACTO EROSION OF THE ATTORNEY-CLIENT PRIVILEGE

- As noted in the 2008 "Filip" memorandum issued by a previous Deputy and codified in the *U.S. Attorneys' Manual,* a "corporation need not disclose, and prosecutors may not request" privileged communications or work product "as a condition for the corporation's eligibility to receive cooperation credit."
- This prohibition expressly includes notes and memoranda from interviews in connection with internal investigations, "so long as the corporation timely discloses *relevant facts* about the putative misconduct."

CONTINUED ATTORNEY CLIENT PRIVILEGE

- While the Filip and Yates memoranda both purport to limit disclosures to strictly "non-privileged" information, the newer memo leaves the door open to the DOJ's implicitly seeking privileged communications, or a waiver, under the auspices of searching for "all relevant facts" necessary for a company to earn cooperation credit.
- While "facts" may not be subject to privilege, the process in gathering them, as well as internal investigation documents (including interview notes, memoranda, and other work product) may be privileged and would be of particular concern if expected to be discussed, especially if the documents contain statements or information on culpable individuals, or if a corporation's internal investigation—aside from privileged documents—was largely unfruitful in identifying culpable individuals.
- This new guidance may complicate a corporation's ability to earn cooperation credit while preserving the attorney-client and work product privileges.

THE GUIDANCE MAY CREATE COMPLICATIONS FOR ENTITIES SEEKING TO RESOLVE CORPORATE ALLEGATIONS WHILE INSULATING INDIVIDUALS FROM LIABILITY.

- Absent "extraordinary circumstances" or "approved departmental policy," the Yates memorandum instructs DOJ attorneys not to—in either criminal or civil matters—"agree to a corporate resolution that includes an agreement to dismiss criminal charges against, or provide immunity for, individual officers or employees."
- Companies seeking to expressly release certain individuals in connection with finalizing a settlement agreement are expected to face significant hurdles in light of this policy instruction.
- Further, investigations will likely take longer to complete since DOJ attorneys will now need to justify and receive approval in the event of a declination to pursue individual charges.

BOARD MEMBERS AND EXECUTIVES MUST REMAIN ATTUNED TO CORPORATE ACTIVITIES.

- With this new emphasis on organization-wide criminal and civil individual accountability, board members and other corporate executives need to remain abreast of company activities and initiatives to the extent necessary to be satisfied that the corporation and its key employees are acting in a manner consistent with the law.
- With the DOJ targeting personnel at the virtual onset of investigations, executive-level personnel may become unwittingly implicated in suspected wrongdoing.
- Internal documentation demonstrating how executives are working in good faith to operate the company in a manner consistent with applicable law, providing prompt responses and solutions to reported issues, among other things, are components that can be used to de-escalate prosecutorial inquiries in their nascence.
- Similarly, board-level efforts to evaluate compliance practices must be maintained and well documented. Increasingly, boards of directors may find it worthwhile to engage their own counsel, independent of that representing the company and management, as they consider potential action possibly adverse to the personal interests of company executives.

- Attempting to "up the ante" in enforcement, the DOJ's Yates memorandum targets individuals and essentially provides that companies must expose them to individual liability in order to receive any kind of cooperation credit.
- While the Yates memorandum does not constitute binding law, its dictates nevertheless apply to all pending matters and future investigations of corporate wrongdoing by the federal government.
- What remains to be seen is what effect this guidance will have on individual prosecutions and corporate resolutions; however, the DOJ's position is unequivocal, and it is clear that, going forward, "[t]he rules have just changed."

REFERENCE AND CITATIONS

George B. Breen, *Stuart M. Gerson*, *and Daniel C. Fundakowski. Epstein Becker Green*

[1] *See* "Individual Accountability for Corporate Wrongdoing," Sept. 9, 2015.
[2] *See* "Deputy Attorney General Sally Quillian Yates Delivers Remarks at New York University School of Law Announcing New Policy on Individual Liability in Matters of Corporate Wrongdoing," Sept. 10, 2015.
[3] U.S. Dep't of Justice, United States Attorneys' Manual 9-28.720 (1999).
[4] *Id.* (emphasis added).
[5] Sally Quillian Yates, Deputy Attorney Gen., U.S. Dep't of Justice, "Deputy Attorney General Sally Quillian Yates Delivers Remarks at New York University School of Law Announcing New Policy on Individual Liability in Matters of Corporate Wrongdoing," (Sept. 10, 2015).

Slides 15-22

RISK BASED INTERNAL AUDITING (RBIA)

RBIA:

- Risk based Internal Audit (**RBIA**) is an internal methodology which is primarily focused on the inherent risk involved in the activities or system and provide assurance that risk is being managed by the management within the defined risk appetite level.
- IIA defines **risk based internal auditing** (RBIA) as a methodology that links **internal auditing** to an organization's overall **risk** management framework. RBIA allows **internal audit** to provide assurance to the board that **risk** management processes are managing risks effectively, in relation to the **risk** appetite.

What is risk?

- Risk is defined as the uncertainty of an event occurring that could have an impact on the achievement of the entity's objectives. Risks can only be minimized by a controlled framework but never completely eliminated. This drives the need for assessments and audits on a continual basis

Inherent Risk, Residual Risk and Fraud Risk

- Inherent Risks are risks that are posed to an entity if there are no controls (i.e., Embezzlement is an inherent risk)
- Residual risk is the risk that remains after controls are taken into account (i.e., day end, week end and month end reporting)
- Fraud risk exists if both persons handling dual custody (Cash and Reporting) collude. The good control for fraud risk will be surprise verification by the internal auditor or members of the management.

SAMPLE RISK BASED AUDIT PLAN

Criticality	Criticality Score	Process Name	Frequency	Corrective Action Plan (CAP)
High	25-30	•Revenue •Human Resources	Quarterly to Semi-Annual	
High	25-30	•Billing /Coding •Clinical Documentation •Medical Necessity	Monthly, Quarterly, Semi-Annual or Annual	
Medium	20-24	•Accounts Payable •Fixed Assets •Compliances (Federal / State	Semi-Annual to Annual	
Low	Below 24	•Administrative Functions	Annual or Bi-Annual	

THE SIX STEPS OF A RISK ASSESSMENT MATRIX

- Step One – Risk Identification – Make sure to assemble all stakeholders and identify all possible project risks. This can be done from various reports, project documents, through various departments and also from prior project reports. The project scope is the rule book that guides the project, therefore all possible risks that the scope indicates will also have to be documented.
- Step Two – Risk Analysis - Some risks may be beneficial, but most risks creates harm and hinders organizations. The risks that are identified have to be analyzed for their probability and impact and also translated into numerical values so as to accurately know the outcome of these risks on the cost, time and resource factors. There are two methods of risk analysis; Qualitative and Quantitative.
- Step Three – Identify Risk Triggers - Divide the risk management team into subgroups and assign segments of the master risk list to each subgroup. The job of each subgroup is to identify triggers or warning signs for each risk on its segment. Document all triggers associated with each risk. *Three triggers per risk are standard*.
- Step Four – Risk Resolution Ideas - Sub-teams identify and document preventive actions for the "threats" and enhancement actions for the "opportunities.“ Risks are unknown events that are inherently neutral. They are characterized as either positive or negative. Equal time should be given to examining opportunities as spent on risk.
- Step Five – Risk Resolution Action Plan - Decide on a plan of action to bring about risk resolution. Risks with a high P-I value will have to be treated with utmost urgency while those with the least probability or impact can just be monitored without having any real action plan. Identifying the most serious risks at the onset of a project saves time, cost and resources, and likewise identification of such risks also trigger the resolution plan at the earliest moment.
- Step Six - Responsibility and Accountability - At the end, the project manager is solely accountable to the project sponsor for all the plans and actions related to the risks and project at large. Proper documentation, such as risk assessment reports, is important during every step of the planning process. A risk management plan should be incorporated into every project management plan. A generic list of risks and triggers can be generated from this initial plan. To apply the risk plan to future projects, simply add project-specific risks and triggers and assess the probability, impact, and detectability for each risk.

DEVELOPING THE RISK MONITORING PROCESS

- *Is Compliance risk monitoring already being performed in different areas of the company?*
  - *The challenge is to coordinate the efforts and bring accountability to reporting potential risks.*
- Develop a "Risk Monitoring (RM) Team" with Key Personnel
  - Areas already monitor or audit for risks?
    - Compliance, Legal, Government Affairs, Internal Audit, HR, Clinical, Information Systems
- Establishing the role of the RM Team
  - Identify potential areas of risks
  - Assess the status of potential risks and how to mitigate damages
  - Review findings and prioritize corrective action
  - Continually monitor risks

- Make certain directives come from Senior Management to implement a risk monitoring process
  - Ensure legal counsel is engaged
- Conduct a GAP Analysis to identify potential risks:
  - Start with your RM Team
  - Interview your Legal Department
  - Interview key members of the organization

Timetables:

- Depending on the size of your organization, it may take months to identify all potential risks and risk areas…
- Schedule regular meetings with the RM Team:
  - To review the risks that have been identified and
  - Assign team members to assess each area of risk
  - Assignments are based on the oversight responsibilities of the individual

- Use a risk assessment template to frame the issue(s) in terms of the requirement and how the potential risk is being controlled.
- If there is a high-probability of noncompliance and potential damage, ensure Legal is involved and that communications are covered under Attorney-Client privilege.
    - Risk monitors need to be aware of this

DOCUMENTATION OF POTENTIAL RISKS

- Develop a template to document potential risks:
  - What are the current regulatory requirements?
  - Who is and should be involved?
  - Determining the status and mitigate risk
  - Potential impact of financial penalties, regulatory oversight, bad press
  - Who is responsible for monitoring risk?
  - How often should we be conducting risk monitoring?

DOCUMENTATION OF RISK STATUS

- Assessing the Status of a Risk
  - Controls in place; no further action steps need to be developed
  - Action steps identified and/or in process of being implemented
  - Part of Internal Audit plan: Date: ____________________
  - Part of Gov't Affairs review: Date: ____________________
  - Need to develop and implement a plan
  - Need to gather more information
  - Assessment complete. No further action or monitoring needed.

DOCUMENTATION OF RISK POTENTIAL

- Potential Likelihood of the Risk Occurring:
  - ❒ High
  - ❒ Medium
  - ❒ Low

- Potential Impact if Risk Occurs *(Check all that apply)*:
  - ❒ High ➔ ❒ Financial ❒ Reg.Oversight ❒ PR
  - ❒ Medium ➔ ❒ Financial ❒ Reg.Oversight ❒ PR
  - ❒ Low ➔ ❒ Financial ❒ Reg.Oversight ❒ PR

- Once the initial assessments are complete, meet with the CRM Team to prioritize all identified risks
- Sort risks based on the:
  - status of their controls
  - likelihood that noncompliance could occur, and
  - potential impact to the company
- Set aside risks that have a low probability and would have low impact

- Inform Senior Leaders that risk(s) have been identified in their area
  - Make sure they know about it, eliminate surprise
  - Gives them opportunity for input
  - Helps you prepare for report to Steering Comm.
- Report to Compliance Steering Committee
  - Give the prioritized risk list to your compliance oversight committee for their review and approval
  - Get their input on prioritization
  - Last step before reporting to the Board

- Report to the Audit & Compliance Committee of the Board
  - Provide Board A&C with high level overview of the compliance risk monitoring process and findings
  - Be prepare to speak to any information that you have documented
  - Be clear about next steps and timing of next report

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  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

ONGOING COMPLIANCE RISK MONITORING

- Establish ongoing risk monitoring that occurs quarterly, semi-annually or annually
  - This should be tied to the initial recommendation on the risk assessment template
- Use the same monitor (from the RM Team) who first helped assess each risk.
  - Consistency is critical to success
- Establish a point person in the Compliance Department to ensure new assessments and updated templates are completed in a timely manner.
- Timing of future monitoring for each risk is based on new assessment findings.
- Use existing audit functions to assess issues where the risk potential is uncertain
  - Add the review of a particular department and process to their annual audit plan
  - Do a formal audit of issues where compliance with state or federal regulations may be in question

CREATING ANNUAL AUDIT ELEMENTS!

2017 Audit Elements	Description of Review	Remedies	Passing Error Rate %	Performed By
1. E&M Coding and Documentation a) Prospective Baseline Review for <u>new</u> providers - 25 office encounters (15 new patient encounters, and 10 established patient encounters b) Annual Prospective Review for all providers - 25 office encounters - 25 hospital encounters, an c) Accuracy of Diagnosis Coding (ICD-10CM)	All chart reviews are performed prospectively unless otherwise identified. E/M chart reviews will be performed using the 1995 E/M documentation guidelines except for those specialties and subspecialties utilizing the 1997 E/M documentation guidelines. For those providers performing in-office procedure there should be a sampling of these when they are billed in conjunction to an E/M and have a modifier applied. For those providers performing these categories of EM Service(s). For any providers not performing these services they will select additional new and established patient encounters. Diagnosis codes must be assigned to the highest level of specificity	If greater than a 5% error rate refer to the Coding and Audit Escalation Policy. If greater than a 5% error rate refer to the Coding and Audit Escalation Policy. If greater than a 5% error rate refer to the Coding and Audit Escalation Policy.	<5% error rate <5% error rate <5% error rate	
2. 99211 Medical Necessity a) In the medical group setting (Incident-To) b) When billed in the Coumadin Clinic. - 20 per year per provider	Incident-To Services must be performed in the physician office setting (refer to Incident-To Guidelines Policy). In the In-Patient setting refer to Split/Shared Services policy. ** There should an extensive review of Incident-To and split/shared services beginning Q1 CY 2017 and completed Q4 CY 2017. Groups where issues are detected should refer to their specific Corrective Action Plan (CAP) for how to proceed in CY 2017. There will be a review of these services as part of your annual audit elements in CY 2017.* Coumadin Clinic guidelines- All services provided in this setting must meet the established guidelines for billing a 99211. There must vitals documented, questions regarding bruising, bleeding or any other abnormal signs or symptoms the patient has identified. There must be education and/or counseling provided and documented by the nurse.	If greater than a 5% error rate refer to the Coding and Audit Escalation Policy. If greater than a 5% error rate refer to the Coding and Audit Escalation Policy.	<5% error rate <5% error rate	
3. Modifiers -25 &/or -59 a) 5 per year per provider 4. Modifier-22 ** 15 per provider if these modifiers are applicable…*	When the Modifier 25 is used on an E/M service in conjunction to a minor procedure the E/M service is considered bundled into the procedure unless the provider is able to demonstrate a "significant, separately	If greater than a 5% error rate refer to the Coding and Audit Escalation Policy.	<5% error rate	

- Compliance risks can be identified at any point during the course of managing a compliance program
- Solicit new risks annually from department leaders
  - People become familiar with roles and process over time
- As new risks are identified and prioritized, add them to the ongoing monitoring process

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