

# Meeting Challenges of the New DOJ Compliance Program Guidelines

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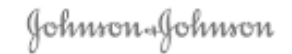
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# Today's Speakers



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# PROGRAM AGENDA

1. History of DOJ CP Guidance
2. DOJ's Fundamental CP Questions
3. CP Design
4. CP applied in earnest & good faith
5. CP work in practice
6. Continuous Improvement & Evolution
7. How to Evidence Meeting Standards



# DOJ GUIDANCE EDUCATES PROSECUTORS

## REPLACES COMPLIANCE EXPERT POSITION

**“Designed to assist prosecutors in making informed decisions as to whether, and to what extent, the CP was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g. monitorship or reporting obligations)”**

**Reviews enable determination if “leniency” is warranted**



# GUIDANCE OVERVIEW

- DOJ's compliance expert advanced DOJ understanding of CPs
- In 2019, DOJ guidance centralized & consolidated existing relevant CP information
- Provides a sharper, clearer CP effectiveness evaluation focus that goes beyond just a surface “paper review”
- Emphasizes on Operation, not Appearance
- Facing enforcement scrutiny, providing satisfactory answers critical
- Since DOJ has found organization in violation of law, little credibility is given to unsupported representations

**Note: DOJ Guidance applies to all sectors; OIG is specific to healthcare**

# “LOOKING UNDER THE HOOD”

- 2020 Guidance has 245 questions/factors in evaluating CPs
  - About doubles the number of 2019 Guidance questions
  - Does not replace 2019 questions, just enhances them
- Digs deeper into CPs, beyond just the “Paper Program”
- Focus on evidence on outcome effectiveness of the CP
- Burden in responding the questions is great
- Doubtful 10% of CPs could meet standards for all questions

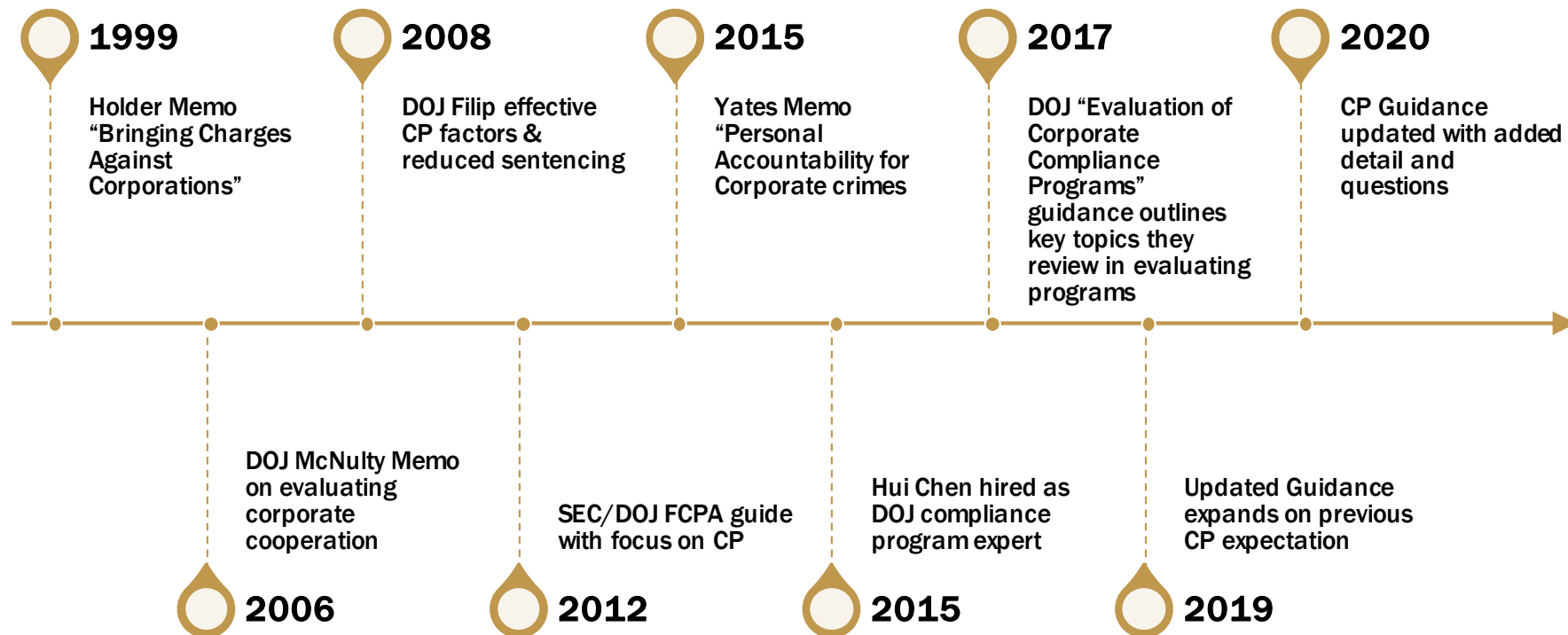
**Tip: Have a “mock CP evaluation” and act upon findings**

# DON'T EXPECT DOJ TO ACCEPT YOUR WORD

FOR PROSECUTORIAL CREDIT MUST PROVE CREDIBLE EVIDENCE

- DOJ evaluations will be with parties found in violation of law
- As such, expect DOJ to distrust representations by entity or CCO
- Representations unsupported with credible evidence is unacceptable
- Credible evidence must be viewed as trustworthy
- Evidence provided must be viewed as credible and trustworthy
- Preference given to evidence developed by independent parties
- Evidence can be qualitative or quantitative, but easily assessable
- Credibility depends on sources of information, conditions of data collection, reliability of measurement, validity of interpretations, and quality control procedures followed

# EVOLUTION OF DOJ COMPLIANCE GUIDANCE



# PRINCIPLES OF FEDERAL PROSECUTION OF BUSINESS ORGANIZATIONS

- “Benczkowski Memo” instructs prosecutors to consider “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” to determine whether a monitor is appropriate.
- DOJ’s Justice Manual describes specific factors prosecutors should consider in determining whether to bring charges, negotiate pleas, or other agreements, including “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”, along with their remedial efforts “to implement an adequate and effective corporate compliance program or to improve an existing one”



# GENERAL GUIDANCE

BOTH DOJ & OIG NOTE A CP IS ALWAYS A WORK IN PROGRESS

**“Is the compliance program being continuously updated to incorporate changing risks, resource needs, and lessons learned from assessments, monitoring, and testing”**

**“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.”**

**Suggestion: Constantly reinforce with leadership/board the message and expectation that the CP is never finished, always work in progress**

# IMPORTANCE OF COMPLIANCE

- **Role of compliance in strategic and operational decisions**
- **Level of experience & qualifications of compliance personnel**
- **CCO direct access and frequency of meetings with board**
- **How funding and personnel decisions are made for the CP**
- **Examples of when CCO raised concerns or objections to specific transactions and company's reaction**

**Suggestion: Document presenting of and approval of proposed CP budget to executive leadership and Board.**

# FUNDAMENTAL QUESTIONS

- 1. DESIGN:** Is corporation's compliance program well designed?
- 2. IMPLEMENTATION:** is program being applied earnestly and in good faith?
- 3. RESULTS:** Does the compliance program work in practice?



# **IS THE COMPLIANCE PROGRAM WELL DESIGNED?**

# DESIGN OF COMPLIANCE PROGRAM

**“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.”**



# **MOVE AWAY FROM “OFF THE SHELF” COMPLIANCE PROGRAMS**

- **Is the CP a “paper program” or one “implemented, reviewed, and revised in an effective manner?”**
- **How has unique circumstances influenced CP development?**
- **Why was CP designed the way it is & how has it evolved?**
- **What was the approach to identify potential issue areas?**
- **Why and how CP was set up the way that it has?**
- **Why and how company’s CP has evolved over time?**

# IS THE PROGRAM WELL DESIGNED?

- Who is responsible for implementation & management?
- How is CP tailored appropriately for the organization?
- How is CP effectiveness of the program tested?
- What risk assessments used to design or update a CP?
- Is risk assessment current and subject to periodic review?
- How has the company been addressing compliance risks?
- Has the most critical risks been adequately addressed?

# IS THE PROGRAM WELL DESIGNED?

- Does compliance have full access to data/information?
- Does compliance play a role in pre-and post-acquisitions?
- Does risk management address 3rd party relationships?
- Are 3rd parties held accountable for compliance?
- Are vendor agreements compatible with the CP?
- Are vendors required to comply with company policies?

**Suggestion: Ensure vendors receive a copy of Code and agree to abide by it and screen their workforce for sanctions.**

# SUFFICIENCY OF COMPLIANCE RESOURCES

- Is the CP adequately resourced?
- Is CP empowered to function effectively?
- Are compliance staff properly qualified?
- Does compliance have widespread support at all levels?
- Are compliance personnel properly trained in their duties?

**Suggestion: Have and execute a training plan for compliance office staff.**

# POLICIES AND PROCEDURES

- How have P/Ps been communicated to employees?
- What compliance policy guidance is provided during training?
- Are P/Ps implemented to incorporate of compliance?
- What evidence that P/Ps are fully understood by employees?
- What guidance is available relating to compliance policies?
- Do employee have easy access/understanding of P/Ps?
- Are P/Ps in “searchable format” for easy reference?

**Suggestions: Standardize form and format all compliance-related policies to be more user-friendly.**



# POLICIES AND PROCEDURES

- How often are compliance P&Ps reviewed & updated?
- Do periodic reviews lead to P&P or control updates?
- Are new/revised P&Ps developed to address risk changes?
- What efforts are made to monitor and update P&Ps?
- Do CP “lessons learned” lead to developing/updating P&Ps?
- Are those policies receiving more attention tracked?

**Suggestion: Have a record management system to keep track on all policy development, review and updating.**

# TRAINING

- Is analysis performed to determine which employees should be trained on what topics?
- Is training in a form & language appropriate for its audience?
- How has leadership communicated its position on detected compliance failures?
- Do policies mandate employee compliance training?
- How is attendance documented?
- Is there a means for measuring CP training effectiveness?
- What evidence is there that training “Truly Effective”?

**Suggestion: Document attendance records, provide test on lessons at end of training and maintain results as part of the compliance records.**

# CONFIDENTIAL REPORTING



**Is anonymous reporting well publicized for employees?**



**How is employee awareness of hotline measured and tested?**



**Is the overall effectiveness of the hotline tested?**



**How is employee “comfort using” hotline measured?**



**How is reporting data (e.g., hotline, anonymous emails) collected, analyzed and acted upon?**



**How are allegations tracked from “from start to finish”?**



**Suggestion: Consider having a compliance knowledge survey that includes asking about awareness of and comfort using hotline**

# INVESTIGATIONS

- Are allegations misconduct promptly investigated
- Are investigations conducted by qualified trained persons?
- Have investigations been properly scoped and documented?
- Are they independently conducted?
- What has been done with the results of its investigations?
- Is information used to assess systemic issues?
- Are root causes for wrongdoing identified and remediated?
- Is there means for responding to investigation's findings?
- How are findings reported and how high up are they reported?

**Suggestion: Ensure those assigned to conduct investigations have received training on basic principles and practice.**



STRATEGIC MANAGEMENT SERVICES

# **APPLICATION OF THE COMPLIANCE PROGRAM**



# APPLY THE PROGRAM IN EARNEST AND IN GOOD FAITH



**Has organization fostered a culture of compliance at all levels?**



**Does compliance have sufficient resources to be effective?**



**Does compliance have sufficient access to relevant sources of data for timely and effective monitoring?**



**Are investigation findings monitored to verify discipline is consistent results across organization?**

# DEMONSTRATE COMMITMENT

- Does management clearly articulate ethical standards to subordinates?
- Does management rigorously enforce Code and policy compliance?
- Does management avoid compliance risks in pursuit of new business?
- Does management support compliance even if it impedes business objectives?
- Does board frequently meet with CCO in executive sessions?
- Does CCO provide regular reports and CP documentation to the board?

**Suggestion: Ensure Board minutes document CCO meetings, including issues addressed and actions taken**

# AUTONOMY AND INDEPENDENCE

- Are there adequate resources for CP to function effectively
- Commitment to compliance at every level
- Emphasis on importance of top to bottom compliance
- Autonomy and independence with un-impeded access to data resources to guide timely and effective program monitoring
- CP direct access to executive leadership and board

**Suggestion: Ensure all meetings with executive leadership and Board are documented and made part of the CP permanent record.**

# MONITORING THIRD-PARTY AGENTS

- Does the company carefully vet agents before retaining them?
- Does the CP apply risk-based due diligence to its 3rd party relationships?
- Is there ongoing monitoring of 3rd party due diligence, training, audits, and/or annual compliance certifications?
- Has company engaged in risk management of 3rd parties throughout the lifespan of the relationship?
- Does the company track “red flags” that are identified from due diligence of third parties and how those red flags are addressed?

# MERGERS & ACQUISITIONS

- Is there comprehensive due diligence of acquisition targets?
- Does CCO engage in compliance pre-acquisition due diligence? (if not, why not?)
- What process is there for timely and orderly integration of acquired entities into existing CP?
- Does company conduct post-acquisition due diligence audits?
- Has misconduct or risk of misconduct been identified during due diligence?
- What is process for tracking and remediating misconduct or risks identified during due diligence?
- Does CCO play a strategic role in M&A decision-making?



# **DOES COMPLIANCE PROGRAM WORK IN PRACTICE**

# DOES THE COMPLIANCE PROGRAM ACTUALLY WORK IN PRACTICE?

- Does company review and adapt its CP based on lessons learned from its own, and other similar companies', or their own experiences?
- Does CCO have “sufficient direct or indirect access to data” to conduct effective monitoring of compliance?

**Suggestion: Document “lessons learned” from audits, reviews, & investigations, as well as from monitoring regulatory and enforcement environment.**

# EMPHASIS ON RISK MANAGEMENT

- Continuous access to data guides risk management
- An iterative approach to third-party risk management and M&A
- Approach to program development that reflects lessons learned
- Analysis and Remediation of Underlying Misconduct
- Annual Risk Assessment are conducted and acted upon
- Continuous Improvement, Periodic Testing, and Review
- Third party management is a priority
- Mergers & Acquisitions (M&A) compliance important

**Suggestion: Have a well-developed annual risk assessment plan**



# RISK MANAGEMENT PROCESS

- How does company identify, analyze, and address risks it faces?
- What information or metrics are used to detect misconduct?
- How have the information or metrics led to CP improvement?
- Disproportionate resources focused on low, not high-risk areas?
- Is the risk assessment current and subject to periodic review?
- Are risk reviews limited to a “snapshot” in time or based upon continuous access to data and information?
- Has periodic review led to updates in P/Ps and controls?
- Do CP updates account for identified risks and misconduct?
- Is there a process for tracking & incorporating lessons learned from internal reviews and those of other organizations?

# ACCOUNTABILITY

**SUGGESTION: ESTABLISH WORKING PROTOCOLS WITH HR INCLUDES TRACKING EMPLOYEE DISCIPLINING FOR COMPLIANCE VIOLATIONS**



How are employees held accountable for misconduct?



What rewards are there for ethical behavior demonstrating commitment to a of compliance



What evidence employees disciplined for compliance failures?



Are managers held accountable for misconduct by subordinates?



Is discipline applied fairly and consistently?



How is compliance and ethical behavior incentivized?



**Suggestion: Establish working protocols with HR includes tracking employee disciplining for compliance violations.**

# REMEDIATION OF DISCOVERED MISCONDUCT

**“A hallmark of a compliance program that is working effectively in practice is the extent to which a company is able to conduct a thoughtful root cause analysis of misconduct and timely and appropriately remediate to address the root causes.”**

# IMPORTANCE OF CORPORATE COMPLIANCE CORPORATE

## MANY QUESTIONS RELATE TO EVIDENCING COMPLIANCE CULTURE

Prosecutors should “assess whether the company has established policies and procedures that incorporate the *culture of compliance* into its day-to-day operation”

Effectiveness of a CP “requires a high-level commitment by company leadership to implement a *culture of compliance* from the middle and the top

“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”

# CORPORATE COMPLIANCE CULTURE

## ARE YOU ABLE TO ANSWER THESE QUESTIONS WITH EVIDENCE?

- Has organization fostered a **culture of compliance** at all levels?
- Have P/Ps been implemented that incorporate the **culture of compliance** into its day-to-day operations?
- Has senior & middle management committed to implementing a **culture of compliance**?
- Does company's **culture of compliance**, include awareness among employees that any criminal conduct, including the conduct underlying the investigation, will not be tolerated?
- Has company created and fostered a **culture of ethics and compliance** with the law at all levels of the company? How?
- What evidence is there of a high-level commitment by leadership to implement a **culture of compliance** from the middle and top?

# COMPLIANCE SURVEYS

**BOTH DOJ AND OIG PROMOTE SURVEYS TO ANSWER QUESTIONS**

- **Has the company surveyed employees to gauge compliance evaluate strength of controls?**
- **Have surveys of employees been used to gauge the culture of compliance and evaluate the strength of controls?**
- **How often and how does the company measure its culture of compliance?**
- **What steps has company taken in response to its measurement of compliance culture?**

**Suggestion: Consider an employee compliance culture survey**

# TWO TYPES OF COMPLIANCE SURVEYS

- **Compliance Knowledge Survey**
  - Uses dichotomous (yes-no) questions testing employee CP knowledge
- **Compliance Culture Survey**
  - Uses Likert Scale questions with gradations of answers to measure employee attitude and perceptions regarding elements of the CP
- Both cited as ways to evidence how well CP functioning, but must be credible
  - Employees trust honesty of process & that their responses won't be tracked back to them
  - Credibility depends on survey meeting tests of validity in accuracy of measurement, and reliability of data obtained

**Suggestion: Limit surveying to one per year and consider alternating between compliance knowledge and compliance culture.**

# CONTINUOUS IMPROVEMENT & EVOLUTION

- Compliance programs are works in progress and are never completed
- CCO “Ongoing Monitoring” of the CP
  - Conduct periodic internal audits
  - Test your controls and utilize tracking systems
- Engage with employees
  - Survey employees to gauge compliance knowledge &
  - Interview employees and 3rd parties to gather compliance data
- Use data to update risk assessment process
  - Review policies, procedures, and practices
  - Focus improvement efforts on high-risk areas



# PERIODIC INDEPENDENT REVIEWS AND ENHANCEMENT

- Does company evaluate periodically CP effectiveness?
- Is there periodic auditing to evaluate CP effectiveness?
- Who reviews CP performance and what is the process?
- Do regular reviews enhance CP in addressing new risks?
- Have periodic reviews led to meaningful changes in its CP?
- Has meaningful CP reviews to ensure program is not stale?
- Has CP been reviewed and audited to areas of misconduct?
- How is CP effectiveness of the program tested?

**CP ongoing monitoring is CCO program responsibility;  
ongoing auditing must be performed by parties independent of the CP**

# 10 TAKE-AWAY POINTS

- 1.** DOJ Guidance more demanding and specific than that of OIG
- 2.** “Paper Programs” worse than no program at all
- 3.** Prosecutors will determine whether leniency is warranted
- 4.** DOJ begins with a position of suspicion of wrongdoers
- 5.** DOJ recognize mistakes happen, question is how are they addressed
- 6.** Leniency not likely w/o credible evidence CP is effective
- 7.** New Guidance, a “deeper dive” on how CP is working in practice
- 8.** Important to meet “culture of compliance” evidence tests
- 9.** Critical to evidence continuous improvement
- 10.** Consider a “Mock Review” to test CP against Guidance

# Polling Question





# Q & A Session



Thank you!