



Leveraging Ethics and Compliance Program Assessments to Enhance Program Effectiveness and Manage Risk

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McKesson at-a-Glance

America's oldest and largest healthcare services company



- Founded in 1833
- Ranked 14th on *Fortune's* list with \$122.7 billion in revenues
- Headquartered in San Francisco
- More than 37,000 employees
- Two segments: Distribution Solutions and Technology Solutions
- #1 pharmaceutical distributor in U.S.
- Deliver **1/3 of all medicines** used each day in U.S.
- #1 generics distributor
- The **fourth-largest pharmacy** network, Health Mart®

Together with our customers and partners, we are creating a sustainable future for healthcare. Together we are charting a course to better health.



Overview of Presentation

- Legal mandates, drivers and guidance for program assessments
- Methodology
- Privilege issues
- Targeted assessments
- Implementing recommendations



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USSG for Organizations Periodic Evaluation Mandate

The organization shall take reasonable steps . . . to evaluate periodically the effectiveness of the organization's compliance and ethics program.

U.S.S.G. 82.1(b)(5)(B)

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DOJ Guidance on Compliance & Ethics Programs

- Corporate prosecution standards amended in 2008 to provide (among other things) that programs should be “reviewed,” which seems to contemplate assessment
- Fundamental Questions:
 - Is the compliance program well designed?
 - Does the compliance program work?
 - Or is it merely a “paper program”?
 - Are employees adequately informed about the program? Convinced of the corporation’s commitment to the program?



Reasons to assess

- Other legal expectations
 - FCPA guidance
 - OECD Good Practice Guidance
 - UK Bribery Act guidance
 - The assessment can be a “road map” for getting program credit in an investigation
- Practical benefits
 - Identifying good practices
 - Identifying areas of potential improvement





Means to Assess

- Interviews
- Document reviews
- Surveys
- Focus groups
- Privilege issue



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Scope of Assessment: Full Program

- Generally all the elements and sub-elements of an effective C&E program
- Plus program “attributes,” – aspects of programs that cut across program elements:
 - Strength/clout
 - Independence
 - Reach
 - Ethics, as well as compliance
 - Management knowledge/involvement in the program
 - Culture



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Assessment through Surveys

- Surveys can provide important data to test employee awareness of the E&C program and comfort level reporting
- Surveys can be repeated over time to provide internal benchmarking and external benchmarking
- Sample question areas:
 - Awareness of chief compliance and ethics officer role
 - Awareness of code of business conduct
 - Awareness of how to report suspected misconduct
 - Comfort level reporting suspected misconduct
 - Perception of company's commitment to ethics & compliance

Note: Can add E&C questions to HR surveys



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“Traditional” Assessment

- Can utilize internal (Internal Audit, Legal) or outside resources to perform
- Can review entire program or particular program areas
 - Reporting and investigations procedures
 - C&E training
 - Program structure
- Can also do “deep dives” into particular risk areas, e.g.,
 - FCPA program assessment
 - Antitrust program assessment
- Privilege question
 - Must be asked and answered before you begin



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Program Elements For Review

1. Program Governance & Accountability
 - Board oversight
 - Management oversight
 - Implementation personnel & resources
 - Documentation of implementation
2. Standards, Procedures & Controls
 - Code of Conduct & compliance policies
 - Distribution of policies
 - Internal controls
3. Diligence in Hiring & Promotions
 - Background checks and delegation of authority



Program Elements For Review

4. Effective Training & Communication
 - Compliance training for employees & directors
 - Compliance communications
5. Compliance Monitoring, Auditing & Reporting
 - Helpline in place, used and concerns addressed
 - Non-retaliation
 - Employee comfort level in coming forward
6. Enforcement, Incentives & Disciplinary Action
7. Remediation of Problems
 - Investigations of suspected violations
 - Discipline for violations
 - Employee incentives for compliance
8. Risk assessment



Program Attributes for Review

- Program resources
- Authority of program
- Independence of program
- Embedding program within the business
- Reach of the program
- Management's knowledge and support of program
- Employee knowledge of and perceptions of program
- Ethical culture



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Methodology: One Example

- Review written policies and procedures and other documentation related to each element of program
- Meet with relevant personnel to obtain additional information regarding development and implementation of each element
- Review sample documents, data and/or reports regarding implementation of each program element



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Methodology: One Example

- Employee surveys, focus groups or both
- Using appropriate standards (next slide), formulate recommendations and review verbally with compliance, legal and other relevant personnel
- Prepare draft report
- Review with compliance and legal
- Prepare final report



Methodology: What Is the Basis of Comparison?

- Legal standards
- Good practices
- Surveys and studies
 - SCCCE
 - HCCA
 - ERC
 - ECOA
 - Conference Board





Privilege/Litigation Issues

- Should consider litigation risks posed by the creation of potentially damaging documents
- Consider:
 - Having assessment authorized by board or senior management for purpose of obtaining legal advice
 - Collecting information under the supervision of counsel
 - Can use in-house counsel



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Privilege/Litigation Issues

- Regardless of whether privilege is used,
- Documentation of assessment should anticipate disclosure
 - "Recommendations"
 - Review with compliance/legal before finalizing the recommendations



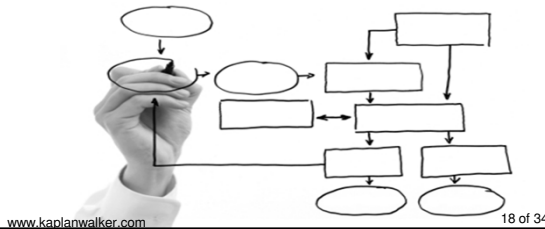
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Closing the Loop

- Final report should include or generate an action plan
- Company may wish to prepare a formal response to the report (if, e.g., company determines not to implement one or more significant recommendations)
- Periodically revisit the action plan (e.g., at the time of formulation of the next program plan or the next program assessment) to ensure that recommendations are being implemented or to generate a response as to why not



Examples of What to Assess Under Elements

- On risk assessment, focus on not only whether the company seems to know its risks but also
 - How well documented the risk assessment process is
 - The extent to which the results of the risk assessment are actually used in designing, improving and deploying various program elements





Elements: Standards & Policies

- Code of conduct – is it
 - On point?
 - Understandable?
 - Being read?
- Individual policies – to what extent
 - Do they seem to address pertinent risks? Get reviewed/revised?
 - Are they “connected” to other program elements, e.g., training and auditing?



Program Governance and Management

- The adequacy of program governance documentation, and not only of the E&C office but also all the other functions with E&C roles, such as members of a E&C management committee, SMEs and regional personnel
- Whether the individuals in these functions are actually doing what the governance documents say they will and the appropriate level of independence and authority to implement the Program
- Whether the Audit Committee is getting the right information, and at the right frequency, about the Program



Diligence in Hiring & Promotions

- Diligence in hiring tends to be pretty straightforward
- But what due diligence steps a company should take regarding promotions is not – and so should try to develop recommendations here based on a company's risks and culture



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Training and Other Communications

- Tends to be among the most extensive parts of a program assessment
- In addition to whether the right people are getting trained on the right topics at the right intervals, should look at efficacy/impact
- This can lead, for some companies, to recommendations for more role based training (and maybe less training)



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Auditing and Monitoring

- Look at the three lines of defense
 - Real time monitoring by businesses
 - Monitoring by functions (e.g., C&E, Finance, HR)
 - Actual auditing
- With each of the above:
 - Is there enough, based on risk assessment
 - Are the results being put to full use?

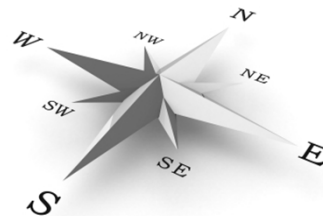
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Reporting Systems

- Should look at
 - Whether reporting procedures and avenues are in place
 - How those are communicated to employees and others
 - Employee comfort level reporting



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Investigations and Discipline

- Are protocols and procedures in place
- How these are implemented in practice
 - Typically includes a review/audit of some case files to get a first-hand look at how investigations are conducted
 - Consider whether investigators are considering and discipline is invoked for supervisory failures that contributed to misconduct in appropriate cases.
- What are employee perceptions of the level of consistency of discipline?



Responses to Misconduct/ Continuous Improvement

- Does the organization have formal procedures for considering enhancements to the Program following violations?
- Are the procedures and practices related to periodic program assessment, including self-assessment?





Incentives

- Does the company use the full range, meaning not just economic incentives, but softer forms?
- Does it deploy not just general incentives but the use, as appropriate, of risk area specific incentives



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Deep Dives

- By risk area, e.g.,
 - Anti-corruption
 - Competition law
 - Note that this may make particular sense for emerging areas of risk
- By program function, e.g.
 - investigations
 - board oversight



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Timing/Frequency of Assessment

- Full surveys plus interviews and document reviews
 - Consider every three years
- Partial - refresher surveys
 - Consider every year



Use of Assessments

- Who gets a copy?
 - Privilege issues
- Using the results
 - Develop an action plan
 - Different levels of priority
 - Board reporting





Breakout Activity #1: Plan a Program Assessment – General Assessment

- Your group is the E&C committee for a 15,000 employee manufacturing company based in the United States but with plants also in 8 other countries (Canada, France, Spain, Poland, Russia, Mexico, Brazil and India). The Board of Directors has instructed you, as CECO, to conduct a program assessment and report back to them in six months. The General Counsel, your boss, has made it clear that she thinks a program assessment is unnecessary at this point, and that you will not be provided resources to hire outside counsel. Create a plan that includes:
 - Who will conduct the assessment
 - Whether it should be under privilege
 - Who will be interviewed, and in what order
 - What documents should be examined
 - Whether there will be a survey and/or focus groups
 - What the deliverables should be, and who should receive them
- How would you handle:
 - Lack of enthusiasm, or resistance, by upper management
 - Discovery of wrongdoing
 - Reluctance to address problems or issues that are unearthed
- What other problems can you foresee, and how may they be addressed?



Breakout Activity #2: Plan a Program Assessment – Risk Area Deep Dive

- Your group is the E&C committee for a 15,000 employee manufacturing company based in the United States but with plants also in 8 other countries (Canada, France, Spain, Poland, Russia, Mexico, Brazil and India). The Board of Directors has been reading the Wall Street Journal, and is a bit concerned about bribery risks. They have instructed you, as CECO, to conduct an assessment of the Company's anti-bribery compliance program and report back to them in six months. The General Counsel, your boss, has made it clear that she thinks a deep dive anti-bribery assessment is unnecessary at this point, and that you will not be provided resources to hire outside counsel. Create a plan that includes:
 - Who will conduct the assessment
 - Whether it should be under privilege
 - Who will be interviewed, and in what order
 - What documents should be examined
 - Whether there will be a survey and/or focus groups
 - What the deliverables should be, and who should receive them
- How would you handle:
 - Lack of enthusiasm, or resistance, by upper management
 - Discovery of wrongdoing
 - Reluctance to address problems or issues that are unearthed
- What other problems can you foresee, and how may they be addressed?



Breakout Activity #3:

Plan a Program Assessment—Program Area Deep Dive

- > Your group is the E&C committee for a 15,000 employee manufacturing company based in the United States but with plants also in 8 other countries (Canada, France, Spain, Poland, Russia, Mexico, Brazil and India). Your CECO recently oversaw an investigation of a bribery allegation in Brazil. Following the most recent update on that investigation, the Audit Committee of the Board of Directors asked the CECO to provide them with more information about E&C investigations. They have instructed you, as CECO, to conduct an assessment of the Company's reporting and investigations procedures and practices, and have asked you to report back to them in six months. The General Counsel, your boss, has made it clear that she thinks a deep dive reporting and investigations assessment is unnecessary at this point, and that you will not be provided resources to hire outside counsel. Create a plan that includes:
 - Who will conduct the assessment
 - Whether it should be under privilege
 - Who will be interviewed, and in what order
 - What documents should be examined
 - Whether there will be a survey and/or focus groups
 - What the deliverables should be, and who should receive them
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