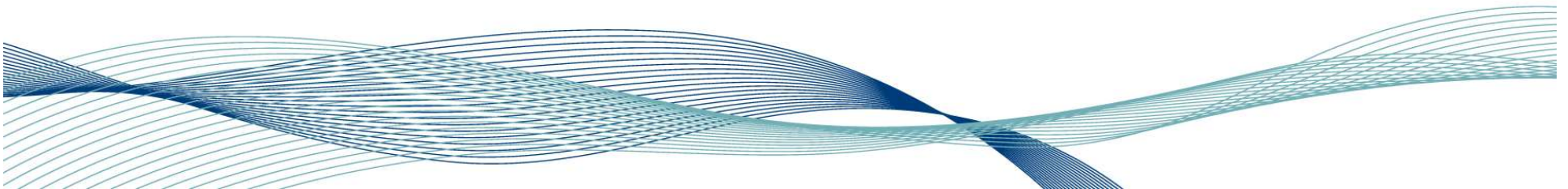**PotomacRiver**
P A R T N E R S

The OIG-HCCA Resource Guide Through a Small to Midsized Pharma Company Lens

CBI Pharmaceutical Compliance Congress
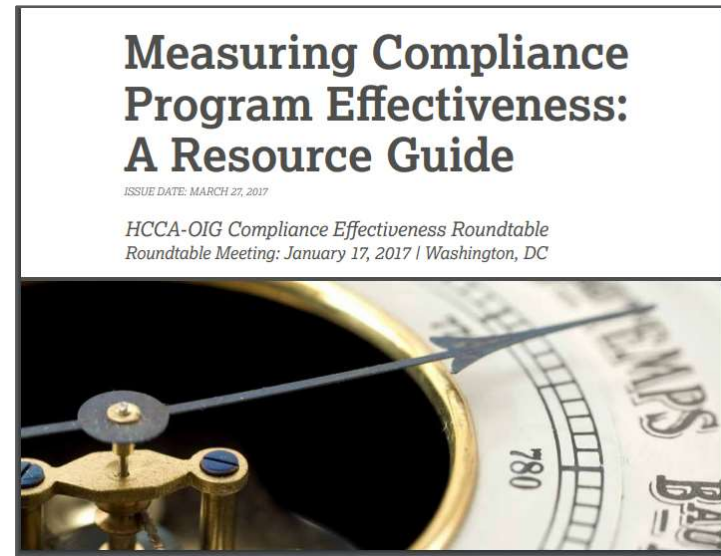**April 25, 2017**

Introductions

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Background

- OIG met with compliance professionals from HCCA

- "To provide a **large** number of ideas"

- Developed **options** for "a wide range of organizations"
  - Diverse size and complexity
  - Industry
  - Resources
  - Compliance Programs

- Organized recommendations largely via traditional 7-Element structure

Measuring Compliance Program Effectiveness: A Resource Guide

ISSUE DATE: MARCH 27, 2017

HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017 | Washington, DC

Challenges with the OIG-HCCA Resource Guide

- Data on the document

    - 7 Sections => 109 topics

    - 401 recommendations (what / how to measure)

    - Nearly 15,000 words

    - Reading level = 12.5

- Inconsistent terminology (e.g., "SOC" vs. "Code")

- Redundancies

    - Review charter of committee – 2.10, 2.11, 2.12

    - Exit interviews to assess retaliation – 2.55, 5.76, 7.57, 7.58

Goals of Our Presentation

- Apply Small to Midsized Company

- Apply Pharmaceutical / Biotech Lens

- Building vs. Maintaining

- A Trip to the Olympics

Gold Medal => Novel idea or very good idea rarely adopted AND easy to implement

Silver Medal => Good idea OR Very good idea that is challenging to implement

Bronze Medal => Generally known idea OR foundational but often overlooked

You Should Not Be Here If…

You do not have a:
1. Code of Conduct
2. Speak Up Policy/Process (e.g. hotline)
3. Risk Assessment
4. Policies on High Risk Areas
5. Monitoring Plan

Consider leaving if you don't have any of these:
1. Training Plan
2. Chief Compliance Officer Job Description
3. Compliance Committee Charter
4. Exclusion Screening Process
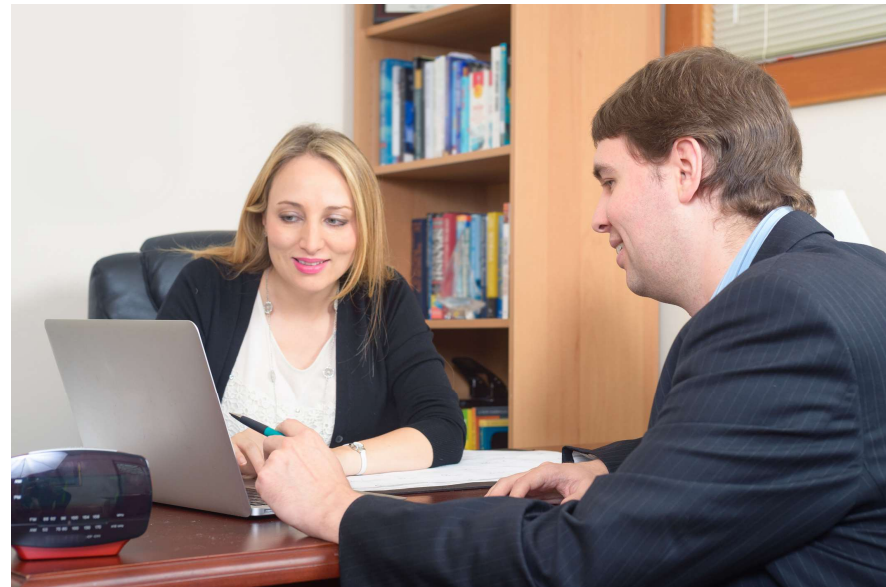5. LMS / Process to Track Training

Gold Medals for Building a Compliance Program

HR Integration

1. Job Descriptions (6.33, 6.34)

2. Onboarding (1.46)

3. Performance Reviews / Promotions (2.48, 2.54, 6.34)

4. Awards, Recognition and Discipline (6.20, 6.34)

5. Exit Interview (2.63)

Gold Medals for Building a Compliance Program

- HR Integration

- **Clarity and Accessibility of Documentation**

1. Flesh-Kincaid Reading Level (1.3, 1.21)

2. Translations (1.22)

3. ADA Compliant (4.16)

4. Accessible by Employees (1.5)

Move from this...

POLICIES

PROCEDURES

...to this.

Gold Medals for Building a Compliance Program

- HR Integration

- Clarity and Accessibility of Documentation

- **Survey Employees Annually**

On Elements

1. Do you know where to locate policies? (1.1., 1.4) Do policies assist you? (1.23)
2. Accessibility of Policies (4.16)
3. Effectiveness of Training (4.17, 4.40)
4. Training Matches Needs (4.21)
5. Confidence in Controls (6.17)
6. Confidence in Risk Assessment (5.34)

Perception of Culture

7. Culture of Compliance (2.31, 4.46, 5.17)
8. Accountability (2.41)
9. Reporting / Confidentiality (4.41, 5.11)
10. Retaliation (5.3, 5.76)

Gold Medals for Building a Compliance Program

- HR Integration

- Clarity and Accessibility of Documentation

- Survey Employees Annually

- **Documents to Store**

1. Conference attendance and budget (2.57, 4.43)

2. Compliance awareness communications (4.26, 4.31)

3. Compliance presentations including committees and sub-committees (2.17, 4.38)

4. Employee recognition activities (4.47)

5. Board presentations (1.11)

Gold Medals for Building a Compliance Program

- HR Integration

- Clarity and Accessibility of Documentation

- Survey Employees Annually

- Documents to Store

- **Role of Compliance Officer and Board**

1. Board to approve Compliance budget and workplan (2.6)

2. Role in Strategic Planning Process and Due Diligence of Acquisitions (2.22)

3. Integration (2.25, 2.38)

4. CO Independence (2.27)

Gold Medals for Building a Compliance Program

- HR Integration

- Clarity and Accessibility of Documentation

- Survey Employees Annually

- Document to Store

- Roles of CO and Board

- **Office Seating & Compensation!**

1. Seating location of Compliance with the business, senior teams are together (2.27)

2. Assess Compliance staff, titles, org chart, pay, promotion records compared to organization (2.38)

Gold Medals for Maintaining a Compliance Program

- **Enhanced Governance (Board, CO, and Comp Committee)**

1. Risk-based budget and compliance plan (2.7, 2.8)

2. Risk-based staffing levels (2.8, 2.35)

3. Process and tools for regulatory changes (2.57, 2.58)

4. Compliance Committee / Leadership Score Card (2.15, 2.9, 2.17, 6.24)

Gold Medals for Maintaining a Compliance Program

- Enhanced Governance (Board, CO, and Comp Committee)

- **Records Auditing**

1. Board Minutes (1.11)

2. Compliance Committee Attendance (2.12)

3. Accessibility of Policies (1.1)

4. Disciplinary Records (2.51)

5. Job Descriptions of Management (3.6)

6. Training Records (e.g., Vendors) (3.33)

7. Exclusion Checks (3.21, 3.37)

8. Implementation of CAPAs (5.37)

Gold Medals for Maintaining a Compliance Program

- Enhanced Governance
  (Board, CO, and Comp Committee)

- Records Auditing

- **Compliance Interviews**

1. Senior Executive Performance (6.33)
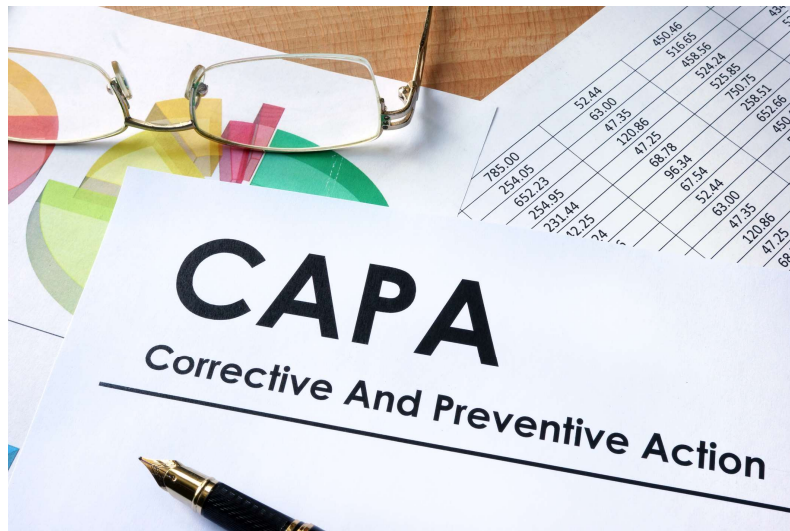2. Policy comprehension (1.21)
3. Vendor exit interviews (3.24)

4. Board of Directors (4.34)

Gold Medals for Maintaining a Compliance Program

- Enhanced Governance
  (Board, CO, and Comp Committee)

- Records Auditing

- Compliance Interviews

- **Robust CAPA Process**

1. Management follow-up (5.66)

2. Is management responsible for corrective action plans? (5.57)
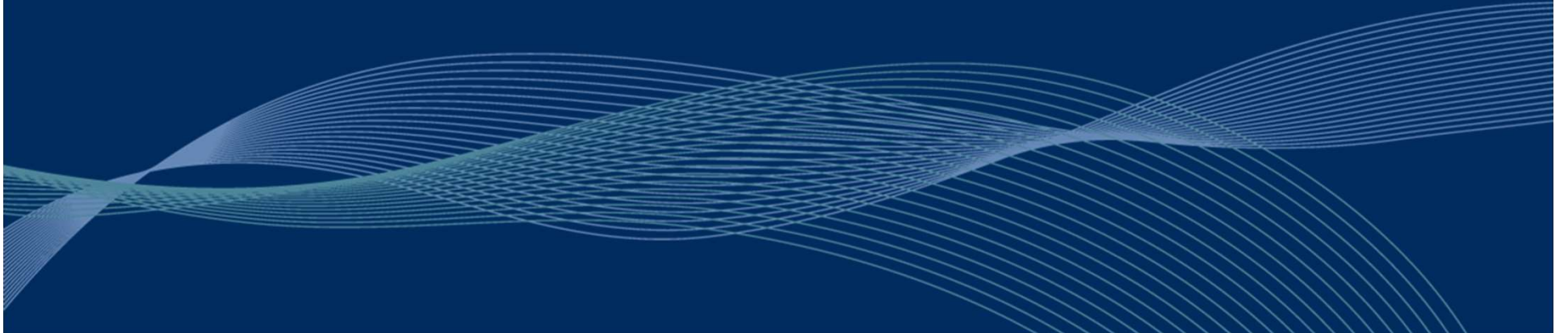
3. Documentation of re-training (4.10)

4. Create dashboard for Compliance Committee of violations (6.22, 7.40)

A Few Additional Thoughts For Our Larger Company Friends

- Documentation Framework (1.18, 1.49, 1.50)

- Tracking policy exceptions (6.27)

- Scale Risk Assessment (5.31)

- Question Tracking (1.54, 4.40)

- Conflicts of Interest Audit (3.3)

Appendix

Other Silver Medals for Building a Compliance Program

- Integrate mission, vision, values, and ethical principles into Code [and Policies] (1.43)

- Maintain records of:
  - Disclosure reports (**not** brought forth through the hotline) (4.11)
  - Policy Exceptions (6.27)

- Develop policy requiring compliance training and education (4.5)
  - Include vendors (4.48)
  - Include a process for capturing material covered, attendees, deployment method, and duration (4.12)

- Conduct test calls of hotline (5.20)

Element #	What to Measure	How to Measure
1.43	Time to investigation closure	• Track timeliness against benchmark established by organization; • Documentation review. Is length to close investigations being documented, tracked, trended and reported?
4.5	The organization has established a process, policy and/or procedure to communicate and provide training to employees on new laws, regulations, policies, and procedures	Conduct a document review to ensure a process for communicating and training employees on new laws, regulations, policies, and procedures has been established and such communication and training is being conducted consistent with the established process.
4.11	The organization tracks disclosure reports (hotline calls, direct contacts to the compliance department) following employee education to determine the extent to which the education was effective at raising employee awareness of specific areas of vulnerability	• Monitor, audit and review disclosure tracking logs to evaluate the effect of education on disclosures. • Track how employees become aware of issues to analyze the effect training has on employee awareness and reporting.
4.12	The organization maintains documentation of all education provided	• Conduct document review and audit to ensure all compliance related education is documented, including material covered, attendees, and deployment method. • Audit to ensure documentation of post-training tests is maintained to evaluate employee level of understanding.

Building: **Other Silver Medals** *(cont'd)*

Element #	What to Measure	How to Measure
4.48	The organization has established the training requirements for vendors	• Conduct document review to ensure the organization has established training requirements for vendors • Review files to ensure vendors have completed training as required • Conduct site visits to review vendor employee completion of required education
5.20	Hotline reporting system/vendor	Monitor. • Are test calls of the system conducted? • Are the calls answered? • If external vendor, are they following the organization's documented notification protocol?
6.27	Policy exceptions	File review of exceptions. Are exceptions tracked, documented, and evaluated? Who gets to make the decision regarding exceptions? Is this process documented?

Other Silver Medals for Maintaining a Compliance Program

- Design a documentation framework and change mgmt. process for new policies (1.18, 1.49)

- Implement risk-based training by "job families" (4.9) and scenario-based training (4.46)

- Conduct knowledge survey 6 months after training is deployed

- Store Compliance staff HR Documents
  - Resume credentials, performance appraisals, certifications, raises, etc.

- Perform a trend analysis of time to respond to incident report (5.9)

- Implement a written escalation process (5.26)

Element #	What to Measure	How to Measure
1.18	Process for review and approving	• Check for written process
1.49	New and updated policy distribution and education of appropriate staff	• Process review - Does organization have formal process to make workforce aware of new policies or changes in policies
4.9	The organization has created their compliance training program around job families to address specific risks identified within a job family.	• Audit the compliance training program to determine if training is tailored to the risks identified and associated with specific job families • Audit to ensure training is assigned based on job families
4.46	The organization has established a culture of compliance	• Survey all employees to determine the extent to which employees believe there is a culture of compliance in the organization and employee understanding of the compliance culture • Review the organization's compliance training material to determine if scenario based training and/or other interactive training methods are used to promote understanding
5.9	Time to respond to incident report	Review date reported, date responded, date investigation closed
5.26	Subordinate conduct	Documentation review. Is there a written procedure to determine at what point a matter must be reported to the board, committee, or government agency?

Building: **HR Integration**

Element #	What to Measure	How to Measure
1.46	Orientation	Audit to ensure all employees receive orientation to the SOC and compliance policies within 30 days of hire
2.48	Aligning performance management system (promotion system) with ethics and compliance objectives	Audit criteria of promotion, bonuses and assignments
2.54	Is compliance taken into account in promotion decisions?	Review promotion lists and documentation to support promotion. Did the individual actively promote compliance?
6.20	Recognition and appreciation	Focus groups, interviews. • Are there recognition and appreciation programs that do not include incentivizing with money? • For example, are there newsletters, reports to governing body, website announcements to recognize those for exhibiting compliance and ethical behaviors and actions?
6.33	Senior executive performance reviews	Process, document review. • Before promotion, does compliance conduct interview to identify or discuss compliance issues? • Does head of compliance participate in the reviews of senior executives? • Is there talk about compliance initiatives with regards to senior executive performance reviews?

Gold	Silver

Element #	What to Measure	How to Measure
6.34	Performance reviews	Document review. • Is there recognition of compliance efforts in performance reviews? • Is compliance built into the performance evaluation for rewarding employees and disciplinary action?
1.43	Integrate mission, vision, values, and ethical principles with code of conduct	Compare code with mission and vision statements to see if it includes elements/statements. Check to see if code is accessible to employees
2.63	Exit interview	Compliance concerns that come up in exit interviews are addressed
3.22	Employee awareness of organization's compliance program	Review organization's employee termination process such as exit interviews, surveys, and/or questionnaires to test for employee awareness of the organization's compliance program

Building: **Clarity and Accessibility of Documentation**

Element #	What to Measure	How to Measure
1.3	Accessible language for code, standards and policies	Flesch Kincaid measuring standard – no more than 10th grade reading level
1.5	Impaired or disabled accessibility	Review accessibility options. Look at methods and speak to individuals
1.21	Language and reading level of policies	Are policies written in plain language, appropriate grade reading level and written in applicable languages for organization? Policy review, Word grade level review and interviews of staff to make sure they understand
1.22	Language translation	Audit or process review. Are policies and the code of conduct translated into appropriate languages for organization?
4.16	The organization has considered the accessibility of compliance education to individuals with disabilities or language barriers and provides education in various formats to accommodate individuals with disabilities or language barriers	Survey employees with communication issues or disabilities to ensure the education was accessible and understandable

Element #	What to Measure	How to Measure
1.1	Accessibility	• Review link to employee accessible website/intranet that includes the Code of Conduct • Survey - Can you readily access or reference policies and procedures? (Yes/No/Don't know) • Survey - How and where do employees actually access policies and procedures? • Test key word search (searchable) • Audit and interview staff to show policies
1.4	Compliance program awareness and communication	• Survey employees to determine the extent to which the code of conduct and other compliance communications are available to employees • Review to ensure the standards, policies, and awareness material is updated and distributed within organization's guidelines
4.16	The organization has considered the accessibility of compliance education to individuals with disabilities or language barriers and provides education in various formats to accommodate individuals with disabilities or language barriers	Survey employees with communication issues or disabilities to ensure the education was accessible and understandable

Building: **Survey Annually – *On Elements* (cont'd)**

Element #	What to Measure	How to Measure
4.17	Employees of the organization perceive compliance education as useful and sufficient to address the compliance requirements in their job	Survey employees to understand their perception of compliance training usefulness and sufficiency
4.40	The organization provides compliance information, training, and updates in a manner that is understandable for employees (reading level, languages, case studies, verbal communication)	Survey employees to determine the effectiveness and level of understanding by employees to the material presented • Conduct post-training evaluations • Review and track questions and disclosures made following the dissemination of information and education
5.34	Is auditing and monitoring based on risk areas identified in risk assessment process	Review risk assessment process and what audits and monitoring are on work plans
1.23	Usefulness	SURVEY - Do department policies and procedures assist you in doing your job effectively? (Yes/No/Don't know)
4.21	The organization solicits feedback from employees on compliance training needs. Employee recommendations are included in training modules disseminated	Conduct document review to ensure employees surveyed for their training/education needs and what feel they need training on. • Interview staff to assess effectiveness of training plan • Confirm that training considers employee feedback

Building: **Survey Annually – *On Elements* (cont'd)**

Element #	What to Measure	How to Measure
6.17	Culture	Survey - Do you feel employees who engage in improper work-related activities will be caught?

Bronze

Building: **Survey Annually – *On Culture***

Element #	What to Measure	How to Measure
2.31	Organizational perception of compliance officer and corporate compliance program	Survey employees regarding: • Their perception of the compliance officer role • Whether they know who the compliance team is, how to get to them and, what to tell them • Is the compliance staff approachable? • Are the compliance staff solution facilitators or looked at as the organizational police force?
2.41	Accountability	SURVEY - Does the compliance department have an impact on how you do your job? (Yes/No/Don't know)
4.41	The organization ensures there is adequate two-way communication between the compliance department staff and employees such as periodic check-ins with employees and follow-up with employees who report concerns	Survey employees to determine: • Their perception of how accessible the compliance staff is, • If they know to report concerns, and • If they believe their concerns are taken seriously and are adequately addressed.

Building: **Survey Annually – *On Culture* (cont'd)**

Element #	What to Measure	How to Measure
4.46	The organization has established a culture of compliance	Survey all employees to determine the extent to which employees believe there is a culture of compliance in the organization and employee understanding of the compliance culture • Review the organization's compliance training material to determine if scenario based training and/or other interactive training methods are used to promote understanding
5.17	Culture Survey	Document review, assessment of responses. Do culture surveys include questions such as: • Do you know how to report concerns? • Are you willing to report concerns? • Do you trust that concerns will be addressed fairly when reported?
5.76	Retaliation	Surveys, focus groups, individual questioning, exit interviews
5.3	Trust in the system	Survey - Do you feel you can freely report ethics and compliance issues without fear of retaliation from managers? (Yes/No/Don't Know)
5.11	Published reporting system	Survey. • Is there a hotline, compliance officer? • How to report? • How to find information?

Building: **Document to Store**

Element #	What to Measure	How to Measure
2.17	Engagement of Directors/Managers	Review committee structure to evaluate how directors/managers are participating in Compliance Operational Committee(s) meeting includes agenda, minutes, attendance and reports from subcommittees
2.57	Compliance staff knowledge of current regulatory changes and laws	Document review and interviews. Review certificates of attendance at conferences/other educational events, "tools" used to keep compliance staff current, compliance budget (to support access to current regulatory changes and laws)
4.26	The organization has established mechanisms to ensure that employees are held accountable for their compliance obligations	• Review job descriptions and performance evaluations for specific compliance metrics • Review Standards of Conduct and other awareness information to ensure compliance obligations are clearly articulated, including the requirement to report compliance concerns
4.43	The organization requires all compliance staff to maintain their competency by attending appropriate educational sessions	Conduct a documentation review to verify that requirements for compliance staff education, including professional development, are established • Audit to verify that compliance staff attend education as required. • Review compliance department budget to ensure sufficient resources are devoted to providing appropriate education (including conferences) to the compliance staff

Building: **Document to Store** *(cont'd)*

Element #	What to Measure	How to Measure
1.11	Annual review and Board approval of Compliance Plan	Audit: Review of Board minutes
4.31	The organization promotes compliance through activities such as Compliance Awareness Week, Compliance Fairs, or other employee involvement activities	Review if and how the organization engages in activities designed to promote compliance awareness
4.47	The organization has established methods for rewarding and recognizing employees for compliance activities	Review incentive, rewards, and recognitions programs to ensure successful achievement of compliance metrics are considered when recognizing and rewarding employees and leadership
4.38	The compliance department/staff regularly present compliance program information and updates at staff meetings, other department meetings, board meetings, town halls, and other forums	Conduct a document review to ensure the compliance department/staff regularly provide updates to the organization and is a visible presence at various meetings. • Confirm the organization documents and tracks all such presentations

Building: **Roles of Compliance Officer and Board**

Element #	What to Measure	How to Measure
2.6	Appropriate oversight of budget	Review charter of governing body (Board) to verify it includes approval of compliance budget
2.22	Is the compliance officer a key stakeholder in the strategic initiatives of the organization	Review participation of compliance officer in strategic planning process and due diligence processes
2.25	Compliance integration	Audit to determine the extent to which compliance officer is involved in training, policy development, marketing and other operational aspects of the business
2.38	Compliance organization	Assess the positioning and effectiveness of the compliance organization staff, titles, organizational chart, pay, promotion records compared to other areas within the organization

Building: **Roles of Compliance Officer and Board** *(cont'd)*

Element #	What to Measure	How to Measure
2.27	Compliance officer's independence/objectivity	• Review compliance officer's job description. Does s/he report directly to CEO, board (not CFO or Legal)? Conduct interviews, focused groups, audit • Seating location of compliance with the business, senior teams are together, and dotted line on org chart • Interview compliance officer to see if they feel they have independence, do they document disagreements, is there executive session for audit committee • Interview the board, review minutes, and interview the CCO • Review of written organizational structure • Verify the Compliance Officer has the independent authority to retain outside legal counsel • Review if there is screening of compliance officer material to the Board of Directors • Regular executive session of the Compliance Officer with the Audit and Compliance Committee of the Board

Gold

Building: **Office Seating & Compensation**

Element #	What to Measure	How to Measure
2.27	Compliance officer's independence/objectivity	• Review compliance officer's job description. Does s/he report directly to CEO, board (not CFO or Legal)? Conduct interviews, focused groups, audit • Seating location of compliance with the business, senior teams are together, and dotted line on org chart • Interview compliance officer to see if they feel they have independence, do they document disagreements, is there executive session for audit committee • Interview the board, review minutes, and interview the CCO • Review of written organizational structure • Verify the Compliance Officer has the independent authority to retain outside legal counsel • Review if there is screening of compliance officer material to the Board of Directors • Regular executive session of the Compliance Officer with the Audit and Compliance Committee of the Board
2.38	Compliance organization	Assess the positioning and effectiveness of the compliance organization staff, titles, organizational chart, pay, promotion records compared to other areas within the organization

Maintenance: **Enhanced Governance**

Element #	What to Measure	How to Measure
2.7	Budget is based on an assessment of risk and program improvement/effectiveness	Is the Board's approval of the budget based on identified risks and effectiveness evaluation/program improvement?
2.8	Sufficient compliance program resources (budget, staffing)	Review budget and staffing to ensure significant risks are managed appropriately
2.9	Active involvement of compliance committee members	Track percentage of attendance of each compliance committee member over the last year
2.15	Effectiveness of compliance committee meetings	Keep executive report card by member qualitative/quantitative with indicators of contribution on topics
2.17	Engagement of Directors/Managers	Review committee structure to evaluate how directors/managers are participating in Compliance Operational Committee(s) meeting includes agenda, minutes, attendance and reports from subcommittees
2.35	Adequacy of compliance staff based on risk assessment	Risk assessment considers the number and competency of staff required to address risk
2.57	Compliance staff knowledge of current regulatory changes and laws	Document review and interviews. Review certificates of attendance at conferences/other educational events, "tools" used to keep compliance staff current, compliance budget (to support access to current regulatory changes and laws)

Maintenance: **Enhanced Governance** *(cont'd)*

Element #	What to Measure	How to Measure
6.24	Compliance in business plans	Document, process review. • Is there a leadership scorecard that includes compliance metrics? • Are there compliance incentives built into business plans?
2.58	Monitoring of regulations that impact the organization	Document and process review, interviews. • Is there a policy and procedure? • Is there evidence that regulations, etc. are disseminated and implemented? • Are there designated individual(s) that monitor laws, regulations, policies that impact organization? • How do they get the information and what do they do with it to make sure it gets to the right people?

Gold   Silver

Maintenance: **Records Auditing**

Element #	What to Measure	How to Measure
1.11	Annual review and Board approval of Compliance Plan	Audit: Review of Board minutes
2.12	Compliance committee composition and attendance	Review charter and minutes to assure attendance
2.51	Proper alignment of compliance objectives with organizational performance incentives (promotions/performance appraisals/bonuses)	• Audit disciplinary records and performance evaluations for consistency with compliance • Audit/Review of process for performance incentives (promotions/performance appraisals/bonuses) criteria to include compliance components
3.6	Accountability for compliance is clearly articulated in employee job descriptions	Audit job descriptions to ensure compliance obligations are clearly articulated
3.37	The organization has established a policy prohibiting vendors that are excluded from working in the organization	Audit exclusions to ensure policy is being adhered to
5.37	Method to create audit plan	Document/process review • What internally and externally are used to create the risk based plan? • Is a review of submitted corrective action plans included in the review and planning process?

Element #	What to Measure	How to Measure
1.1	Accessibility	• Review link to employee accessible website/intranet that includes the Code of Conduct • Survey - Can you readily access or reference policies and procedures? (Yes/No/Don't know) • Survey - How and where do employees actually access policies and procedures? • Test key word search (searchable) • Audit and interview staff to show policies
3.21	The organization has a policy and procedure which articulates the process for screening, investigation of potential "hits," actions taken in response to a positive finding, tracking exclusions, and communication to appropriate stakeholders	Conduct documentation review and audit to ensure screening is being completed according to policy requirements and that all process elements related to investigation, resolution, tracking, and communication are being managed according to policy requirements
3.33	Vendors and other 3rd parties adequately satisfy compliance obligations	Conduct audit of vendors and other 3rd parties to ensure they have documented evidence of required compliance training, orientation to the organizations Standards of Conduct, orientation to applicable compliance policies and procedures

Maintenance: **Compliance Interviews**

Element #	What to Measure	How to Measure
1.21	Language and reading level of policies	Are policies written in plain language, appropriate grade reading level and written in applicable languages for organization? Policy review, Word grade level review and interviews of staff to make sure they understand
3.24	Vendors and other 3rd parties are interviewed at the termination of the engagement and asked about their awareness of the compliance program and any concerns, risks, violations, or failures of the compliance program	Review organization's vendor termination/off-boarding process such as interviews, surveys, and/or questionnaires to ensure compliance program questions are incorporated into the process and interviews/results are reviewed and evaluated
6.33	Senior executive performance reviews	Process, document review. • Before promotion, does compliance conduct interview to identify or discuss compliance issues? • Does head of compliance participate in the reviews of senior executives? • Is there talk about compliance initiatives with regards to senior executive performance reviews?
4.34	The organization's training plan provides for specific education that will be provided to the Board and senior executives. The plan includes the topics that will be covered, the frequency of training, includes current industry developments and resources, and provides education on their responsibilities for compliance	Review training materials provided to the Board and senior executives and conduct personal interviews to ensure training is provided pursuant to the plan and the level of understanding of the material presented

Maintenance: **Robust CAPA Process**

Element #	What to Measure	How to Measure
4.10	The organization evaluates policy and compliance failures and provides re-education to applicable staff	Audit files of known policy or compliance failures to ensure re-training is considered as part of corrective action • Audit to ensure the re-training is completed • Track for reoccurrences to determine the effectiveness of the re-training and employee understanding
5.57	Compliance audit results	Process review and document review • Are audit results being analyzed, tracked, trended and reported? • For example, how often are education or policies and procedure changes needed? • Is management (not compliance) responsible for corrective action plans? • Is compliance monitoring corrective action plans to completion and then conducting follow-up audits to ensure the actions remain in place?
5.37	Method to create audit plan	Document/process review. • What internally and externally are used to create the risk based plan? • Is a review of submitted corrective action plans included in the review and planning process?
5.66	Corrective Action Plans	Document review. Audit • Is there a documented follow up process to make sure management has completed items in corrective action plans? • Were the corrective actions successful in correcting the deficiency? • Are follow up audits conducted to ensure corrective actions do not lapse?
6.22	Oversight	Review minutes for number of disciplinary actions for compliance and HIPAA violations in last year reported to the Compliance Committee (dashboard)

Maintenance: **Robust CAPA Process** *(cont'd)*

Element #	What to Measure	How to Measure
7.40	Time to investigation closure	• Track timeliness against benchmark established by organization; • Documentation review. Is length to close investigations being documented, tracked, trended and reported?

Other Bronze Medals for Maintaining a Compliance Program

Bronze

- Store the following documents
  - o Compliance Plan
  - o Board ratification of Compliance Plan
  - o Training records
  - o Hotline calls
  - o Discipline records