

Putting Compliance into Use – Beyond the Basics



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Objectives

- Considerations and practical advice on operationalizing compliance into multiple line of business within the same organization
- Identify challenges commonly experienced by organizations attempting to operationalize compliance for large and small organizations

What Does “put it into use” Mean?

- “To make something functional and able to be used by others”. “Operationalize”
- To operationalize, compliance must be integrated into business processes
- Sounds simple but given how highly regulated healthcare services are, operationalization needs to be intentional and functional to be successful.

Objective #1

- Considerations and practical advice on operationalizing compliance into multiple line of business within the same organization

Compliance Program Gap Analysis

Risk Assessment is a key component of measuring Compliance Program effectiveness and was included in two Compliance Program Effectiveness guidance documents released in 2017 by the Office of Inspector General (OIG) and the Department of Justice (DOJ):

- Measuring Compliance Program Effectiveness: A Resource Guide (HCCA-OIG Compliance Effectiveness Roundtable,
- U. S. Department of Justice (DOJ) Compliance Program Effectiveness documents

Measuring Compliance Program Effectiveness: A Resource Guide

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*HCCA-OIG Compliance Effectiveness Roundtable
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Gap Analysis

Element 1: Standards, Policies, and Procedures			Comments
What to Measure			
Access:			
1.1	Accessibility	<ul style="list-style-type: none"> • 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 	
1.2	Actual Access	Audit how many actual "hits" on policies and procedures	
1.3	Accessible language for code, standards and policies	Flesch Kincaid measuring standard – no more than 10th grade reading level	
1.4	Compliance program awareness and communication	<ul style="list-style-type: none"> • 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 	
1.5	Impaired or disabled accessibility	Review accessibility options. Look at methods and speak to individuals.	
1.6	Policy communication	Communication strategy of policies	
1.7	Availability of policy content	Conduct surveys and observation	
Accountability:			
1.8	Accountability	Policy Coordinator designated	
1.9	Ownership and accountability of policies	Audit process of how policies get enforced by chain of command when compliance is not the final approver. Is management taking responsibility for implementing and following policies?	
1.10	Routine policies and procedures	Confirm that listed owner of each policy and procedure is the actual owner.	
Review/Approval Process:			
← Element 1 Element 2 Element 3 Element 4 Element 5 Element 6 Element 7 DOJ Evaluation Elements →			

Compliance Program Effectiveness Surveys

- Survey Monkey
- Launch through your electronic learning system
- Paper
- Email
- Completed by third-party

Compliance Program Effectiveness Surveys

- Do you know where to locate Compliance policies and procedures?
- Do you know where to find the most current version of the code of Ethics and Business Conduct?
- Do you know who the Chief Compliance Officer is?
- How do you educate your stakeholders about the Compliance policies and procedures and where to find them?
- Do you receive information from your leadership about new/updated Compliance policies?
- Do you refer to Compliance policies and procedures during the performance of your job duties?

Compliance Program Effectiveness Surveys

- Do you ensure all new stakeholders complete all assigned Compliance training by the assigned due dates?
- Do you know where to refer compliance questions, including those regarding patient privacy and potential disclosures of protected health information (PHI)?
- Do your stakeholders know where to refer compliance questions, including those regarding patient privacy and potential disclosures of PHI?
- Do you know where and who to report potential Compliance violations, including HIPAA violations?
- Is your staff informed that they will not be retaliated against for reporting possible violations in good faith?

Compliance Program Effectiveness Surveys

- Do residents or POAs receive and knowledge receipt of the Notice of Privacy Practices upon admission?
- Does your facility have a process and designated contact for reporting and tracking applicable disclosures?
- Does your facility have a process for documenting requests for the restriction of uses and disclosure of PHI?
- Does your facility have a whiteboard, bulletin board, or any other display with PHI written/posted on it?
- What is required to provide a copy of a medical record to a resident?
- What is required if an individual, other than the resident, requests a copy of a medical record.
- Who do you contact when equipment that may contain PHI is either lost or stolen?

Compliance Culture/Effectiveness Survey

- I am familiar with the company's compliance program.
- I know where to find a copy of the code of conduct.
- I am aware of the compliance hotline and how to access it.
- I know how to contact the compliance department if I have a question.
- I am aware of where to find the policies and procedures related to my job.
- I know where the compliance policies and procedures can be located.
- My management team supports the goals and objective of the compliance program.
- My co-workers encourage ethical and compliant behavior (doing the right thing).

Compliance Culture/Effectiveness Survey

- If a compliance concern comes to my attention, I would feel comfortable reporting it to my Supervisor/Manager.
- I am comfortable reminding a co-workers if something they are about to do would violate the Code of Conduct or a policy.
- As an associate, have you felt pressure to compromise ethics (moral principles) to get the job done?
- If a compliance concern comes to my attention, I would feel comfortable reporting it to my Administrator.
- If a compliance concern comes to my attention, I would feel comfortable reporting it to my Human Resource Department.

Compliance Culture/Effectiveness Survey

- If a compliance concern comes to my attention, I would feel comfortable reporting it to the Compliance Officer.
- I am confident that the Compliance Department will ensure my compliance concern is addressed and resolved in a timely manner.
- Fear of retaliation would prevent me from reporting a compliance problem.
- During Compliance and Ethics Week, I saw one of the Pet Compliance Posters.
- I have observed workplace behavior that I felt violated the Code of Conduct, policy or law.
 - If yes to the previous question, did you report it to anyone?

Risk Assessment

■ A Compliance Risk Assessment:

- Identifies and prioritizes risk
- Designs controls to protect the organization
- Allocates resources
- Helps development of Internal Audit and Compliance Monitoring plan
- Prevents and reduces compliance issues
- Decreases or prevents potential fines and expense to the organization.



Five Stages of a Risk Assessment Process

Risk Assessment

- Risk Assessments are based in Compliance Program guidance:
 - U. S. Sentencing Guidelines (USSG § 8B2.1(b)(5)(7) and (c); USAM 9-28.800 Comment; OECD Handbook, B, p. 10 *et seq.*)
 - Office of Inspector General (OIG) Compliance Program Guidance
 - Corporate Integrity Agreements, Risk Assessment and Internal Review Process requirement.

Risk Assessment

- Annually, a team conducts a risk assessment and internal review process using a team approach if possible. May include Compliance, Internal Audit, Legal and Operations, in order to:
 - Identify and address risks associated with participation in Federal health care programs
 - Including, but not limited to, the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries
- Various ways to do it
- Develop best method for your organization and scale it to organization's complexity
- Best practice is to develop a Risk Assessment policy and follow it annually

Risk Assessment

- The risk assessment process may include:
 - Compliance Effectiveness Gap Analysis
 - Review of government documents
 - Review of regulatory changes and payment changes
 - Review of internal reports
 - Data mining
 - Interviews
 - Surveys

Risk Assessment

- The risk assessment process includes review of:
 - Government Documents
 - OIG Work Plan and updates for audit areas that are applicable
 - OIG Audit results
 - Corporate Integrity Agreements
 - Department of Justice settlement agreements
 - Advisory opinions
 - Fraud alerts
 - PEPPER reports
 - State and federal survey results
 - Other government publications for risk areas that may be applicable

Risk Assessment

- The risk assessment process includes review of internal reports for potential areas to review or follow-up:
 - Internal risk scorecards
 - Prior audit results
 - Government audit results
 - Exit interview
 - Hotline call trends
 - Investigation trends
 - Risk management cases
 - QAPI
 - Facility Assessments
 - Data Mining

Risk Assessment

- Review regulatory changes and emerging legislation/regulations that could impact the organization, such as:
 - Changes in government payment models
 - Implementation of new regulations
- It's also important to take the additional areas listed on the next slide for consideration:

Risk Assessment

- Bad Debt
- Billing and Coding
- Clinical Quality
- Clinical Research
- Cost Reports
- Credentialing
- Credit Balances
- Documentation
- Emergency Preparedness
- Environmental
- Excluded providers
- Finance
- HIPAA Privacy and Security
- Information Technology
- Licensure
- Marketing
- Medical Necessity
- Mergers, Acquisitions and Divestitures
- Physician Transactions (Stark)
- Policies and Procedures
- Record Retention
- Regulatory
- Reimbursement
- Staffing and Payroll Based Journal
- State and Federal Surveys

Compliance Risk Questionnaire

- What are your key areas of concern for 2019 and 2020 fiscal year?
- What are your key processes, functions and/or controls that are subject to frequent breakdowns or at the greatest risk of breaking down?
- What are the most important things you are working on and how could they fail?
- What is your process for monitoring issues and how that information is reported? What is your method for distributing new regulations or policy changes?

Compliance Risk Questionnaire

- What is the process for training the department on internal/external requirements?
- What is the process for developing and updating the department policies and procedures and verifying they are being accurately implemented?
- Is there anything you foresee coming down the road (mergers, acquisitions, joint venture, etc.)?
- Other areas of comment or concern?

Claims Based Risk Assessment

- Identify Risks based on:
 - MAC, RAC, CERT MDS and Claim Top Errors
 - OIG Report and Work Plan
 - Internal Audits
 - Interdisciplinary Team and Operations Surveys
 - Data Integrity Audit Reports
 - Compliance and Reimbursement Site Visit Reports (handout)
 - Therapy Systems Assessment Findings (Handout)
 - IRO Results

Compliance and Reimbursement Site Visit Reports

- Includes MDS accuracy, skilled coverage guidelines, care coordination and IDT Team assessment areas, such a:
 - Eligibility
 - Certification/Recertification
 - MDS Audit
 - Submissions and Validation
 - MDS Logic Verification
 - Care Plans
 - Liability Notices
 - Nursing Narrative Notes
 - Meetings
 - Therapy
 - Triple Check
 - Benefits Exhaust

Therapy Systems Assessment

- Onsite team visit: Compliance, Reimbursement and Rehab Mgmt including Clinical Performance Specialist (2-4 participants)
- 1 ½ - 2 days performing:
 - Observations:
 - Gym, IDT Meetings, Daily PPS, Triple Check
 - Interview
 - Documentation Reviews
- Results shared in a huddle with all rehab, the IDT/Medicare Team
- Action plans are created for any areas with opportunities

Post Risk Assessment Action

- Once risks have been identified, there are various ways to rank them:
 - Red, yellow, green
 - Low, moderate, high
 - Numeric ranking
 - By likelihood of occurrence – improbable, remote, occasional, frequently, all the time
 - Impact of occurrence – minimal/negligible, slight, moderate, critical/serious, catastrophic
 - Categorically by type of impact, such as compliance, financial, legal and reputational

Work Plans

- Use prioritized results from the Risk Assessment to develop work plans:
 - Develop Compliance Monitoring Plan
 - Develop Internal Audit Plan
- Have Compliance Committee and Board approve plans – the OIG expects it!



Sample Risk Assessment Process Timeline

- Third Quarter – Develop Risk Assessment questions, compliance effectiveness survey and assess OIG Work Plan and schedule interviews.
- Beginning Fourth Quarter – Launch Risk Assessment process with documentation review, interviews with key management and compliance effectiveness survey (allow a month to complete)
- Mid-Fourth Quarter – Review and risk rank results of interviews and compliance effectiveness survey (allows two weeks to complete)
- Late Fourth Quarter – Develop Internal Audit Plan, Compliance Monitoring Plan, Compliance Plan and any action plans and present to Compliance Committee and Board for approval
- First Quarter – Launch Internal Audit Plan, Compliance Monitoring Plan, Compliance Plan and implement any action plans
- Repeat Cycle

Work Plans

- What should you include in monitoring and auditing?
 - Education completion
 - Hotline call analysis (types of calls, number of calls, by entity/region/state)
 - Whether hotline calls were logged within 2 business days
 - Repayments within 60 days (government audits, internal audits, compliance monitoring, investigations)
 - Staffing ratios against state mandates
 - Star ratings
 - Expired licenses
 - Excluded providers
 - Billing reviews
 - HIPAA Privacy and Security

Work Plans

- Conduct auditing and monitoring and report out findings to management, the Compliance Committee and the Board
- Develop Corrective Action Plans with owner
- Conduct follow-up to test effectiveness of Action Plans
- Document, document, document

Sample Compliance Monitoring Plan for FY 20xx						
Description of Monitoring Activity	Risk	Frequency	Sample Size	Assigned To	Date Completed	Results
Annual Compliance Education	Failure to meet Federal Sentencing Guidelines	Annually	100%			
Hotline Compliance Calls and Compliance Investigations	Ineffective Compliance Program	Monthly	100%			
Repayments within 60 Days	CMS 60-Day Payment Rule, False Claims Act	Monthly	100%			
Excluded Employees, Vendors, Physicians	Federal Sentencing Guidelines	Monthly	100%			
Licensure - CNAs, PLNs, RNs PT, OT, SLP and Other	State Law	Monthly	100%			
Management Certifications	Ineffective Compliance Program	Annually	100%			
Conduct gap analysis of Compliance Program with the OIGs and DOJ's guidance and develop action plan	Ineffective Compliance Program	Annually	100%			
Compliance/Privacy Self Assessment	Ineffective Compliance Program	Annually	100%			

Objective #2

- Identify challenges commonly experienced by organizations attempting to operationalize compliance for large and small organizations

Prevention Challenges

Structure,
Onboarding,
Education

Structure

- Compliance tone and conduct should start at the top and cascade down into the deepest level of an organization and a clear structure is key
- Structure reduces the likelihood compliance messaging and initiatives will get lost in translation
- Establishing clear structure helps improve transparency
- Structure can help reduce the impact turnover can have for ongoing compliance

Structure/Staffing

- Structure varies significantly depending on ownership, size, resources and potential additional factors (CIA)
 - Board(s)
 - Board Committee(s)
 - Corporate or Chief Compliance Officer
 - Regional or Agency Specific Compliance Officers
 - **Compliance Liaisons**
 - Other Internal Resources

Phase 3 RoP Compliance & Ethics - REVISED

- Operating organizations with five or more facilities must include these additional components in their compliance and ethics programs:
 - Have a more formal program that includes established written policies defining the standards and procedures to be followed by its employees.
 - Develop a compliance and ethics program that is appropriate for the complexity of the operating organization and its facilities.
 - The operating organization for each facility must periodically review and revise its compliance program to identify necessary changes within the organization and its facilities.

Compliance Liaison

- Serve as the Compliance Liaison for the community.
- The Compliance Liaison champions compliance activities for all departments under their supervision and assumes responsibility to:
 - Raise and maintain compliance awareness in community;
 - Lead by example;
 - Understand, identify and address risk areas;
 - Support a proactive approach towards investigation and resolving potential compliance issues;
 - Communicate information on compliance priorities to department supervisors and staff;
 - Provide oversight to ensure corporate compliance training is completed timely during orientation and annually for all staff;
 - Assist in planning and implementation of community specific training sessions as deemed necessary;
 - Assist in development of and provide oversight to ensure effective auditing/monitoring plans are in place.
- Transparently report issues and collaborate with Corporate Compliance Officer.

Compliance Liaison

- Who is the ideal candidate to wear the extra hat as Compliance Liaison?
 - Administrator
 - Grievance Coordinator
 - Medical Records Coordinator
 - Social Services
 - HR
 - Educator
 - Chaplain
 - Building by building selection

Compliance Liaison

- What else to consider when implementing Compliance Liaisons?
 - Policy describing the Compliance Liaison's roles and responsibilities
 - Job description or supplemental Job Description if wearing multiple hats
 - Communication plan
 - Education
 - Monitoring tools
 - Additional compensation
 - Turnover plan

Onboard/Education Challenges

- Employees
- New Board Members
- Health Care Services Vendors
 - Medical Directors
 - Consultants: Social Services; Dietitians; Activities
 - Labs, Mobile X-ray, etc...
- Volunteers
- Role Specific Competency

Education

- Compliance Training
 - Single training, periodic or short burst trainings?
 - Style: LMS, live, webinars, mobile apps, posters, newsletters, email blasts
- Role Specific Training
- Compliance Program Promotions
 - Compliance and Ethics Week Activities (Handout)
 - Branding

Performance Metrics

- Is compliance tied to performance measures?
 - Are there incentives or measures for timely completion of compliance training in performance evaluations?
 - Do performance metrics include adherence to the Code of Conduct?
 - Do bonus plans or other incentive plans incorporate compliance considerations?

Sample Performance Measure Liaisons

Compliance/Code of Conduct:

Emphasizes the importance of ethics and compliance through frequent communications evidencing an appropriate “tone at the top”. Increases employee awareness about the importance of making ethical decisions through frequent communications about ethics and compliance. Ensures that direct and indirect reports received compliance training that is appropriate to their respective roles at the organization. Ensures that direct and indirect reports participate in compliance training program. Actively takes steps to implement the company’s compliance program and its code of conduct.

Select One:

- Substantially Meets
- Meets most of the time
- Improvement needed
(indicate action plan in the improvement plan section on the next page.)

Sample Performance Measure for Associates

Compliance/Code of Conduct:

Participates in and supports the compliance program (as evidenced by completion of all compliance related training). Uses the company's code of conduct in the performance of all work and/or to answer questions; encourages other employees to do the same. Demonstrates a willingness to challenge questionable conduct, if witnessed, in the course of employment. Strengthens decision-making skills by understanding policies and laws pertaining to their role and proactively taking compliance/ethics into account when making decisions on the job.

Comments/Examples:

Select One:

- Substantially Meets
- Meets most of the time
- Improvement needed
(indicate action plan in the improvement plan section on the next page.)

Detection Challenges

- Auditing
- Data Analysis
- Monitoring

Data Analysis and Reporting

- One of the greatest issues in healthcare is that the volume of data available is expansive.
- The volume of and the number of sources of data can be overwhelming.
- Data that is meaningful needs to be communicated to:
 - Board
 - Compliance Committee
 - Operations
 - Legal
 - Compliance Liaisons

Data Analysis, Auditing, Monitoring

- There are numerous ways to review and report data.
- Determine data priorities and reporting responsibilities and then tailor the report to your key audiences.
- May take many forms such as Compliance Reports or Compliance Dashboards.

Corporate Compliance Report

(DATE)	FOR (QUARTER)		
TRAINING AND EDUCATION			
Type	Completion Target	Actual	
New Hire Compliance (Month)	100%		
REPAYMENTS (Detail is included in the Compliance Report)			
Resulting From	Number	Repayment Amount	Paid Within 60 Days
Internal Audit/Monitoring			
Internal Investigation			
Government Audit			
Total			
EXCLUDED PROVIDERS			
Type	Number	Repayment	
Employees			
Physicians/Providers			
Vendors			
EXPIRED LICENSES		STAFFING RATIOS	
Expired licenses	Cost Report Adj.	Number out of compliance	Number receiving citations

Incident Management

- Excel
- SharePoint
- Access Database
- Online Platforms

Corrective Actions

- After exit with Audit or Compliance on findings, Operations is responsible for creating the CAP.
- CAPS may require final approval by Compliance and/or Audit before implementation.
- Management has ownership and signs off when CAP is in place.
- Use a post implementation tool to verify interventions/corrections were effective.
- Establish periodic ongoing monitoring.
- If under outside scrutiny, they will expect to see documentation of the CAPS implemented and testing to ensure effectiveness.

Monitoring Effectiveness

- This can be one of the most challenging pieces to correction due to limited resources and competing priorities
- Must carve out time to ensure that the corrective action was and is still effective by testing it
- Consider pulling department specific monitoring up into a centralized audit platform to be reviewed by compliance and internal audit

Key Takeaways

- To get to “organization”
 - Determine the current status of the program
 - Identify and prioritize risks
 - Create structure that is functional
 - Make reports meaningful
 - Ensure that organization responds to identified issues
 - Document, document, document

Contact Information

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