



Compliance Policies and Procedures 101
How to Develop and MANGE Your Compliance Policies

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How to Develop and Manage Your Compliance Policies

Your Hosts



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The material in this presentation is general background information about the matters described herein, and is for informational purposes only. This information is given in summary form and does not purport to be complete. This information should not be considered legal or financial advice. You should consult with an attorney or other professional to determine what may be best for your individual needs.

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Polling Question

I am interested in learning more about compliance Policy and Procedures (P&P) because _____.

- a. I approve P&P or I am on a P&P committee
- b. I draft or review P&P
- c. I am hoping to obtain a position which may involve P&P
- d. I am just generally interested



Importance of Compliance Policies & Procedures

Why is it important to have robust Policies, Procedures, and a Code of Conduct?

They are an essential element of an effective compliance program,
and
they may be the difference between fines/penalties and a Corporate Integrity Agreement.



Importance of Compliance Policies & Procedures

The first element of The Office of Inspector General's Seven Fundamental Elements of an Effective Compliance Program is "Implementing written policies, procedures, and standards of conduct."

Not only is it the first element of an effective program—policies are also a valuable resources for both the compliance program and employees because they:

- Provide documentation of how the organization conducts business in compliance with professional standards and state/federal laws and regulations;
- Standardize process and operations across multiple practice locations;
- Provide workforce with clear, concise guidance; and
- Reduce institutional risk through accountability.



Polling Question

A policy is a “statement that is the guide to any decision making in relation to processes or activities that regularly take place or might be expected to occur.”

If you had a visit from the DOJ and were asked if your policies adequately and succinctly guide your organization’s workforce in decision-making that helps them achieve rational outcomes, how confident are you that you could make a successful argument and back it up with policies?

1. Very Confident
2. Somewhat Confident
3. Vote of No Confidence



Irving, Anne, *Policies and Procedures for Healthcare Organizations: A Risk Management Perspective*, Patient Safety & Quality Healthcare (Oct. 13, 2014), <https://www.psqh.com/analysis/policies-and-procedures-for-healthcare-organizations-a-risk-management-perspective/>

Department of Justice Guidance

Policies are so important that the DOJ’s Evaluation of Corporate Compliance Programs Guidance Document specifically states:

“[P]rosecutors should examine ‘the comprehensiveness of the compliance program,’ . . . ensuring that there is not only a clear message that misconduct is not tolerated, but also **policies and procedures** – from appropriate assignments of responsibility, to training programs, to systems of incentives and discipline – that ensure the compliance program is well-integrated into the company’s operations and workforce.”



U.S. Department of Justice Criminal Division, Evaluation of Corporate Compliance Programs Guidance Document (April 2019), <https://www.justice.gov/criminal-fraud/page/file/937501/download> (emphasis added).

Department of Justice Guidance

Furthermore...

“Any well-designed compliance program entails **policies and procedures** that give both content and effect to ethical norms and that address and aim to reduce risks identified by the company as part of its risk assessment process. As a threshold matter, prosecutors should examine whether the company has a **code of conduct** that sets forth, among other things, the company’s commitment to full compliance with relevant Federal laws that is accessible and applicable to all company employees. As a corollary, prosecutors should also assess whether the company has established **policies and procedures** that incorporate the culture of compliance into its day-to-day operations.”



U.S. Department of Justice Criminal Division, Evaluation of Corporate Compliance Programs Guidance Document (April 2019), <https://www.justice.gov/criminal-fraud/page/file/937501/download> (emphasis added).

The Organization’s Code of Conduct

Organizations should have a Code of Conduct that details the organizations expectations for anyone working on their behalf.

- It should incorporate the organization’s mission, vision, and values.
- Should have clear and concise language about how and to whom to report actual or suspected misconduct or non-compliance with the organization’s expectations.
- It must have language explaining that retaliation for good faith reporting of misconduct will not be tolerated.
- Annual attestation that the code has been received and read should be obtained and kept for historical purposes.



Categorizing the Compliance Policies

Most compliance programs include policies and procedures (P&P) that fall into two categories:

1. Policies & Procedures relating to the operations of the Compliance Program, such as:
 - Information regarding the compliance program;
 - Mechanisms for reporting;
 - Defining non-compliance;
 - Expectations regarding employee conduct; and
 - Corrective action/ disciplinary actions for violations.
2. Policies & Procedures addressing the organization's significant compliance-related risk (may vary based on the type of organization)

Self Evaluation of the Organization's Policies and Procedures

In evaluating the organization's policies & procedures the compliance professional should consider:

- Is the policy manual comprehensive?
- Does the manual include policies and procedures that incorporate a culture of compliance in the day-to-day operations?
- Are the policies and procedures aimed at reducing risk to the organization through well-defined and easily understandable content?
- Are the policies and procedures aligned with industry standards?

Self Evaluation of the Organization's Policies and Procedures continued...

- Do the policies and procedures address accreditation/certification requirements?
- Are there gaps identified in the risk assessment? (varies based on organization type and activities)
- Do the policies and procedures address Part C and Part D Sponsor attestation requirements?
- Are appropriate policy owners designated and are they aware of their responsibilities as policy owners?

Polling Question

How many compliance policies are published to your organization?

- a. Less than 10
- b. 10-25
- c. Over 25

Compliance Policies—Are They Comprehensive?

OIG Recommended P&P:

- Coding and Overpayment
- **Non-retaliation**
- **Internal and External Compliance Audits**
- Record Retention
- Conflict of Interest
- Confidentiality
- Privacy
- **Regulatory Requirements: EMTALA, CLIA, Anti-kickback, Research, Labor laws, Stark, False Claims, etc.**
- Interactions with Industry Representatives
- Compliance and Quality of Care Issues
- Gifts and Gratuities
- **Incentives and Disciplinary Standards**
- Waiver of Copayments and Deductibles
- **Code of Conduct**
- **Governance for Compliance Program**

Measuring Compliance Program Effectiveness – A Resource Guide, HCCA-OIG Compliance Effectiveness Roundtable Meeting (January 17, 2017)

CMS Manuals - Compliance Program P&P:

- **Compliance with Federal and State Standards**
- **Standards of Conduct**
- Reporting suspected or detected compliance issues and Compliance hotline
- **Compliance investigations** and expectation that employees assist in resolution
- **Non-intimidation and Non-retaliation**
- Compliance Training
- **Disciplinary Standards**
- Identification of Non-compliance and Unethical Behavior
- Compliance Risk Assessment and FWA Risk Areas
- **Compliance Reporting Structure**
- Contracting with the Government
- Protected Classes

Medicare Managed Care Manual, Chapter 21, and Prescription Drug Benefit Manual, Chapter 9, Compliance Program Guidelines (January 11, 2013)

Moving Forward to Developing Meaningful Policies



Structure

1. Develop a structure

- Policy on Policies:
 - What is the process for requesting a new policy or revision to an existing one?
 - Formal process through official request form versus informal request
 - Is there a standard template that is used to capture all information prior to submission?
 - What is the request based on?
 - Identified through regulatory guidance;
 - Identified through annual risk assessment; or
 - Identified due to a self-report of deficiency.
 - Will the policy apply to the entire organization or is it department specific?

Standard

2. Adopt a Standard

- Uniform template/format:
 - Standardize headings - common headings include: Title, Policy Number, Purpose, Responsibilities, Definitions, Scope/Applicability, Review Date and Effective Date, Related P&Ps, Sanctions for Violations, etc.
- Policy selection:
 - How are submissions selected for policy development?
 - What is policy and what is protocol/procedure?
 - Policies are largely static and are a group of rules or directives.
 - In contrast, procedures define the specific set of actions that meet the policies in everyday operations.
 - Procedures are essentially the who, what, when, and where of applying policy statements to daily operations.
- Documented history of revisions:
 - Will the submission replace an existing policy?
 - Does the submission incorporate several policies?

Numbering & Title

3. Numbering:

- Determine how your policies will be organized:
 - By Location (Ambulatory, Hospital, Site/State, etc.);
 - By Purpose/ownership (Compliance, Health Information Management, (HIM), Privacy, Security, Legal, etc.); or
 - By Entity
 - Adopt a simple numbering structure if all policies will apply to all locations and employees.

4. Title:

- Title in such a way that the policy is searchable. If common acronyms are used, include them in the title.
 - Examples:
 - Emergency Medical Treatment and Active Labor Act (EMTALA)
 - Kentucky All Schedule Prescription Electronic Reporting (KASPER)

Definitions, Applicability, & Accessibility

5. Definitions:

- Define key phrases, words, or terms that help the reader to understand the importance of the policy.

6. Applicability & Accessibility:

- Do policies address the purpose, function, and authority of the Compliance Program?
- Does the policy apply to all employees?
- Is the policy specific to a unit/department/division?

Content

7. Content:

- Consider the language;
 - Use simple language, such as the 8th grade reading level.
- Incorporate common name/define acronyms;
- Use examples;
- Avoid policy provisions that cannot be implement/executed; and
- Verify appropriate uses of must/may/should/shall

Consequences & Reporting Options

8. Consequences for non-compliance:

- Policies should include provisions for corrective action of non-compliance.
- Do all infractions carry the same weight?
- Is corrective action progressive?
- Policies should include language for immediate termination.

9. Reporting Options:

- Always include reporting options
 - Phone, mail, email, anonymous hot-line.
- Avoid names as individuals may leave or change roles.

Related Policies & Review Cycle

10. Related Policies:

- If you have policies that link together or are related, list and hyper-link them if possible.

11. Review Cycle:

- Establish a review cycle, such as every 2-3 years or when a substantial change is needed.
 - Review more frequently if required by law
- Always include the original policy date and include date of revisions or review.

Onward to Implementation



Department of Justice Guidance

“Prosecutors should assess the steps taken by the company to ensure that policies and procedures have been integrated into the organization, including through periodic training and certification for all directors, officers, relevant employees, and, where appropriate, agents and business partners.”



U.S. Department of Justice Criminal Division, Evaluation of Corporate Compliance Programs Guidance Document (April 2019), <https://www.justice.gov/criminal-fraud/page/file/937501/download> (emphasis added).

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Considerations

The main considerations when implementing new or revised policies and procedures include:

- Approval/Responsibility;
- Communication/Dissemination Plans;
- Accessibility; and
- Review and Effectiveness



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Self Evaluation of the Organization's Policies and Procedures

- Are there individuals or groups that approve the policies, procedures, and the Code of Conduct? Is there, or should there be, a Policy and Procedure Committee?
- What is the communication plan to ensure employees are aware of policy or Code of Conduct updates?
- Has an appropriate review schedule been established? When was the last time the review schedule was evaluated? Is the review schedule being followed?
- Are employees aware of how to access policies? Do employees believe there are any gaps in the policies and can they demonstrate an understanding of the policies, procedures, and code of conduct?

Responsibility and Approvals

Operational Responsibility:

- Who has operational oversight of Policy Management?
 - Depending on the size of your organization you may have a policy coordinator, policy and procedure committee(s), and/or department specific oversight plans.
- Ensure operational/business stakeholders are involved to ensure the policies and procedures are reinforced and included in related trainings.

Policy Approval:

- Verify there is a formal approval process for policies, procedures, and the code of conduct.
 - Audit the process to ensure it is being followed.

Communication and Dissemination

Communication and Dissemination:

- Consider the process for new policies vs. updated policies.
- Verify employees and stakeholders are informed when new policies are published or existing policies are updated.
 - If the policy or procedure will require operational changes, communicate with the stakeholders as early as possible.
- New hire vs. current employees vs. third party (contractors, agents, vendors, volunteers)
 - New Hires should be provided a unique or generic log on during orientation to allow them immediately access policies.

Communication and Dissemination Continued...

Training/Acknowledgment/Attestations

- What is the plan for training on policies, procedures, and the Code of Conduct?
- Must employees annually acknowledge or attest to receipt?
- Is there testing for knowledge/ understanding/competency?

Accessibility

It's not enough to have Policies, Procedures, and Code of Conduct; instead, organizations must demonstrate their commitment to ensuring access to these resources.

- If your organization has foreign subsidiaries, determine if there are communication barriers that need to be addressed.
- Make sure these resources are readily available to your employees and consider the extent they are made available to non-English speaking and persons with disabilities.
- Your organization should also determine whether its policies and procedures are only available internally or are publicly available.
 - Operational/business stakeholders and policy owners must be made aware of the scope of accessibility.

Effectiveness

Effectiveness:

- Implement mechanisms to assess whether the policies, procedures, and code of conduct are understood by employees and business stakeholders.
 - Interviews, observations, surveys, audits, questionnaires, review test scores from trainings, etc.
 - Is there a trend in reports related to certain policies and/or procedures?
- Seek feedback on whether there are any gaps in the current policy resources.
- Consider whether job aids or cognitive aids will improve adherence or streamline operations.

Review

Review Schedule:

- Ensure review schedules are implemented and being followed.
- Utilize effectiveness feedback when considering policy resource revisions.
 - Look at corrective actions based on policy violations?
 - Was the corrective actions due to lack of understanding of policy?
 - Was the language/guidance vague?
 - More than one corrective action for the same reason?



Questions?



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