Developing the Framework for your Compliance Program Policies & Procedures

Sunday, April 17 from 9:00 AM – 12:00 PM

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In this morning's session, we will discuss:

- How do you develop policies and procedures
- What policies, procedures, and guidelines do you need for your Compliance Program
- What are some ideas for managing the policies, procedures, and guidelines for your Compliance Program and your entire organization

How Do You Develop Policies and Procedures
Code of Conduct

A code of conduct is a set of rules outlining the social norms and rules and responsibilities of, or proper practices for, an individual, party or organization. Related concepts include ethical, honor, moral codes and religious laws.

Wikipedia

Your Organization’s Code of Conduct

- Ethical attitude of your Organization
- Emphasis on compliance with all applicable laws and regulations and adherence to Organization values
- Applies to all employees, governing body, partners and all representatives
- Reflect the culture, business, corporate identity
- Should be easy to understand and concise
Code of Conduct – Employees and Others

- Annual attestation for all employees and governing body
- Training program should include the Code
- Consistent enforcement of Code compliance is crucial
- The Code should clearly state the discipline for noncompliance

Does Your Organization Need Policies and Procedures

- How will employees know how to act?
  - Performance Reviews
  - Accountability
  - Enforcement of Discipline

- Positive impact on workflow and efficiency
- Results in consistent behavior and practices and provides clarity
Policy vs. Procedure vs. Guideline

- **Policy**: Clear statement of rules the employees are to follow
- **Procedure**: Methods used to put policies into action day-to-day
- **Guidelines**: Expressions of the boundaries of the policies and determine decisions and actions

How are They Different

**Policies**
- Have widespread application
- Are non-negotiable, change infrequently
- Are expressed in broad terms
- Are statements of what and/or why
- Answer major operational issues

**Procedures**
- Have a narrower focus
- Are subject to change and continuous improvement
- Are a more detailed description of activities
- Are statements of how, when and/or who & sometimes what
- Detail a process
Elements of a Policy

- Title
- Policy number
- Department/Area
- Purpose statement
- Definitions
- Responsible party
- Effective date
- Review date
- Other references and policies/procedures
- Policy applies to whom
- Effect of non-compliance

Policy Development

- What is the policy in regards to?
- What Departments are impacted?
- Is the policy driven by regulatory or law?
- Policy applies to whom
- Effect of non-compliance
- Does a sub-committee need to be convened to develop policy?
- Who “owns” the policy?
- Are there existing policies on the same subject matter? Does this policy replace an existing policy?
### Policy Checklist

<table>
<thead>
<tr>
<th>Planning</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject Matter Experts:</td>
<td>Purpose: (cite any regulations, statutes, company policies, etc.)</td>
</tr>
<tr>
<td>Required Reviewers: (Law, HR, etc)</td>
<td>This is new document or a revision: (specify) Revisions require redlines</td>
</tr>
<tr>
<td>End-User Vetting/Trialing:</td>
<td>AFFECTED BUSINESS UNITS/LINES:</td>
</tr>
<tr>
<td>Required Final Approvals:</td>
<td>SYSTEMS AFFECTED:</td>
</tr>
<tr>
<td>Compliance Committee, Senior Leadership, Board of Directors</td>
<td>Required Training or Education</td>
</tr>
<tr>
<td>Specify if testing is required</td>
<td>Auditing and Monitoring:</td>
</tr>
<tr>
<td>Desired Publication Date:</td>
<td>Responsible Person: Describe who is responsible for implementing the policy in each operational unit</td>
</tr>
<tr>
<td>Publication Method(s):</td>
<td></td>
</tr>
<tr>
<td>Electronically/Email</td>
<td></td>
</tr>
<tr>
<td>Live Training</td>
<td></td>
</tr>
</tbody>
</table>

### Policy Life Cycle

1. **Prepare**
   - Date policy is due
   - Review policy at scheduled times

2. **Draft**
   - Vetting
   - Auditing

3. **Approve**
   - Publishing

4. **Publish**
   - Training/Education
   - Monitoring

5. **Monitor**
   - Review policy at scheduled times

6. **Repeat**
   - Vetting
   - Auditing
CLASS EXERCISE

DEVELOP AN ANNUAL COMPLIANCE TRAINING POLICY

I.e. Slide 11
Who does policy apply to
What are training requirements
What is the effective date
Discipline

CLASS EXERCISE

DEVELOP NON-RETALIATION POLICY

I.e. Slide 11
Who does policy apply to
What are training requirements
What is the effective date
Discipline
CLASS EXERCISE

DEVELOP COMPLIANCE AUDITING AND MONITORING POLICY

I.e. Slide 11
Who does policy apply to
What are training requirements
What is the effective date
Discipline

What policies, procedure and guidelines do you need for your Compliance Program
Policy or Not

- Depending on your industry, you will want to ensure your organization has policies in place to meet the guidance provided by all applicable regulatory authorities.

- Within your organization you need to be active in risk and regulatory monitoring processes to identify when a policy, procedure or process needs to be created.

Examples of Compliance Policies

Policy and Procedure Development Policy

Internal Handling of Ethics Line Calls Policy

Reporting Compliance Issues and Occurrences

Code of Conduct Distribution and Training Policy

Auditing and Monitoring

Records Management Policy
Examples of Compliance Policies

Performance Management/Discipline/Disciplinary Action for Compliance Issues

Equal Employment Opportunity

Non-Retaliation

Fraud, Waste, and Abuse Prevention/Whistleblower Protections

Conflict of Interest Policy (definition and disclosure; gifts)

Examples of Compliance Policies

Entertainment Policy

Ethics and Compliance Officer Policy

Business Courtesies to Potential Referral Sources Policy

Referral Source Arrangements Monitoring

Charges Must be in Relation to Costs
Examples of Compliance Policies

Accuracy of Documentation, Charging, and Billing

Refunding of Overpayments

Ethics and Compliance Program Contracts Policy

Potential Identity Theft Indicators Policy

Information Privacy and Security (ie. Integrated healthcare company website www.tenethealth.com)

Class Discussion

What challenges have you faced in defining compliance policies?

What other compliance policies would be included in this list?

What successes have you had in implementing compliance policies in your organization?
Ideas for managing the policies, procedures and guidelines for your Compliance Program and your entire organization

Managing the Organization Policy Process

1. Policy responsibility should not be spread out within your organization.

2. Policies should exist in multiple mediums so that they are accessible throughout your organization.

3. A policy that is outdated is worse than not have a policy at all.

4. Policies must have an official owner or steward within the organization that is skilled in the area or that will leverage skills of the subject matter experts.
Managing the Organization Policy Process

5. The procedures and methods used to implement a policy will need to encompass means to monitor behavior to ensure policy compliance.

6. Policies should be mapped to standards and regulations to aid in determining the appropriate action the organization should take.

7. Attestation and certification must be integral parts of policy management.

8. Policy management cannot be isolated within the organization.

Forbes Tech article: Avoid potential (and common) pitfalls.

Organizing the Organization Policy Process

- Develop project plan to develop your policy management process
- Establish a policy process committee
  - Make this a subcommittee of your Compliance Committee
- Organize
  - Alphabetically
  - Issue Date
  - By Policy Number
  - By Department
Organizing the Organization Policy Process

- Management approve and issue policy
  - Utilize Compliance Committee for policy approval
- Provide monthly report of policy process/development
- Control issuing authority
- Authoring policy can be delegated
- Controlled delegation

Organizing the Organization Policy Process

- Delegate responsibility
- Be clear and concise
- Document all changes
  - Track all policy changes
    - When, Why and by whom
- Establish Periodic Review Process for all policies
- Organize logically
Organizing the Organization Policy Process

- Communicate updates timely
  - How you will communicate

- Education, Training
  - Document and test compliance

- Encourage feedback

- Provide central access - Using technology to house and distribute
  - Sharepoint
  - Policy Management Technology

Case Study

Your facility CEO has just returned from a meeting in Washington DC where regulators emphasized how important an effective policy management process is to healthcare organizations. He stops by your office and lets you know that you will now be leading the policy management process for the organization.

What do you do now?
Case Study: Group Exercise

- Class will divide into groups and prepare a preliminary project plan.
- Nominate a spokesperson for your group.
- Each group will present their project plan to the class.

Summary

- Maintain compliance-related policies, procedures, and controls (e.g., regulatory requirements, billing and coding)
- Maintain process for the development of new policies for emerging compliance risks
- Consult with applicable resources to assure the policies are comprehensive (e.g., regulatory, legal, subject matter expert)
Summary

- Integrate mission, vision, values, and ethical principles with code of conduct
- Maintain compliance plan and program policy
- Assure that a non-retribution/non-retaliation policy exists

Summary

- Maintain policies and procedures for internal and external compliance audits
- Maintain a code of conduct
- Verify appropriate policies on interactions with other healthcare industry stakeholders (i.e., hospitals/physicians, pham/device representatives, vendors, etc.)
Summary

- Assure policies and procedures address the compliance role in quality of care issues
- Promote accountability (e.g., incentives, sanctions, disciplinary policies) for employees at all levels
- Maintain a compliance department operations manual
- Assure governance policies related to compliance are appropriately maintained

Questions?

Thank You for being a part of our class!
Appendix – OIG Guidance

OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the healthcare industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

The compliance program guidance documents are listed on the next 4 slides.

09-30-2008

11-28-2005
NSTC Launches Government-Wide Initiative Based on OIG Draft Guidance for HHS Research Grants (June 7, 2006)
Appendix – OIG Guidance

01-31-2005

05-05-2003

03-24-2003

10-05-2000

03-16-2000

11-15-1999
Compliance Program Guidance for Medicare+Choice Organizations (64 Fed. Reg. 61893; November 15, 1999)
Appendix – OIG Guidance

**10-05-1999**
Compliance Program Guidance for Hospices (64 Fed. Reg. 54031; October 5, 1999)

**07-06-1999**

**12-18-1998**

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**08-24-1998**

**08-07-1998**

**02-23-1998**
Appendix - CMS Guidance

Compliance Program Policy and Guidance
Federal regulations at 42 C.F.R. §§ 422.503 and 423.504 specify the requirements for Medicare Plans to implement an effective Compliance Program.

Compliance Program Guidelines
The Compliance Program Guidelines reflect CMS' interpretation of the Compliance Program requirements and related provisions. These guidelines were issued as Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. Both Chapters are identical and apply equally to the Medicare Advantage Organizations and Prescription Drug Plan Sponsors.