Healthcare Compliance Program
Development: Structure and Beyond

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Why Develop a Healthcare Compliance Program?

- Promotes a culture of ethical behavior, awareness and commitment to compliance
- Prevents and detects wrong-doing
- Communicates organizational expectations and commitment
- Provides “safe” mechanisms for reporting and seeking help
- Enables compliance with governing standards, laws and guidelines
- Positive impact to corporate reputation/culture; public image
- Serves as a risk management tool
Health Care Compliance Programs: How Comprehensive

- Provider documentation
- Non-retaliation
- Research
- Data Protection (Privacy and Security)

Benefits of an Effective Health Care Compliance Program

- Integrates processes that ensure the prompt, thorough investigation of alleged misconduct
- Facilitates timely and appropriate corrective action and remediation
- Fosters a strong ethical culture -- Attracts talent and improves employee retention
- Strengthens the organization
General Considerations: Structure First …

- “Tone at the Top”
- Establish organizational governance (i.e., Designation of Compliance Officer)
  - Reporting structure defined
  - Compliance Oversight Committee
    - Include providers
  - Resources (people, budget, etc.)
    - Marketing, communications, staffing
General Considerations: Tools

- Conduct risk assessment
- Implement reporting system (i.e., Hotline)
- Tracking processes
- Education and Training
- Managing Investigations
- Auditing and Monitoring

Key Elements in Developing a Health Care Compliance Programs

1. Standards and Procedures (including the Code of Conduct)
2. Compliance Oversight
3. Education and Training
4. Monitoring and Auditing
5. Reporting, Investigations and Background Checks
6. Enforcement and Discipline
7. Response and Prevention
Standards & Procedures

- **Code of Conduct**
  - Keep it simple – Values-based and avoid legalese
  - Tailor to organization’s culture, ethical attitude, business, and corporate identity
    - Get lots of input - focus groups, senior execs., etc.
  - Guidance on seeking help and reporting concerns
  - Scenarios and FAQs
  - Clearly stated expectations
  - Annual attestations
  - Primary language – watch translations

- **Policies and Procedures**
  - Controls – Facilitate compliance and prevent misconduct
  - Accountability
  - Integrate with and complement other departmental policies and procedures
  - Avoid repetition/duplication
  - Assure those affected by the policies have input into development
  - Communication and distribution of standards and procedures to employees and others (i.e. third parties)
Examples of Health Care Compliance Policies and Procedures

- Provider Documentation
- Non-retaliation
- Record Retention
- Privacy
- Security
- Conflict of Interest

- What are others?

Compliance Oversight

- Governing Authority – Knowledgeable of program w/reasonable oversight (Board of Directors)
- Compliance Officer – Oversight for day to day operations
  - Recognized as a senior leader
  - Independent and empowered (i.e. adequate resources and authority)
  - Access to Board with periodic reporting responsibilities
- Other: Compliance Committees, Regional liaisons, Program Staff, etc.
Compliance Oversight: Due Care in Delegation of Authority

• Do hiring and promotion systems screen out those likely to break the law or who have a history of unethical behavior?
  – Use care when placing individuals in positions of substantial authority, i.e., hiring, promotions – *Substantial Authority Personnel*

• Could you have a Board Member, executive or other manager who had served time for a criminal act without knowing it
  – CEO resigned, served prison time – “Nobody asked”

Education and Training

- General vs. Specific – Content and Audience Considerations
  - Example: Ethics – general, Provider documentation - specific
- Mandatory vs. Voluntary – Audience & Risk Considerations
- Training Methods
  - Blended & Interactive approach is most effective
- Tracking all training
- Communication and Training Effectiveness – *Continual review*
Monitoring and Auditing

- Primary purpose is prevention and detection of compliance issues
- Definitions:
  - Monitoring - Real time reviews done by everyone, not necessarily independent
  - Audits – Always independent/objective and formalized
- Audit and monitoring plan scalable to risks and resources
- Auditors must be trained and knowledgeable about audit methodology.

Reporting, Investigations and Background Checks

- Reporting
  - Essential program resource for reporting wrong-doing and/or seeking help and guidance
  - Reporting process defined
  - Expectations are clearly defined for those that raise issues
  - Consider differing country laws for operation
  - Anonymous & confidential to extent allowed by law
  - Need strong, publicized and enforced non-retaliation policy
  - Continually market and publicize reporting mechanism
  - Consider internal vs. external reporting systems
Reporting, Investigations and Background Checks

Investigations
- Define response time expectations
- Triaging and handling investigations
  - Investigations should be professional – trained investigators
  - Consider the process for report writing
  - Consider the decision-making process for handling findings
- Action is comprehensive related to the potential/real concern
  - Are there enough facts to investigate?
- Consider attorney-client privilege

• Background checks
  - Determine what background checks are important for compliance
  - Assure there is a process for conducting background checks
  - Legality of background checks are determined by country laws
  - Expectations should be clear on what happens if there is a positive outcome
    - Consideration should include privacy laws, organization’s obligations, timing to resolve issues
    - Must take action


**Enforcement and Discipline**

- Failure to take reasonable steps to prevent or detect criminal conduct heightens organizational liability and negatively impacts effectiveness determinations.
- Compliance performance aligned with incentives.
- Consistency in enforcement:
  - Support from Sr. Mgmt; Board.
  - Understanding by all members of organization.
  - Fairness and consistency is key.

**Response and Prevention**

- Preventative measures:
  - Education and Awareness.
  - Policies and Procedures.
  - Auditing and Monitoring.
- Remediation efforts are timely and adequately address the program gaps, identified risks, etc.
  - Resolution of Issues – Root cause analysis/checklist.
  - Management Corrective Action Plans.
  - Prevents likelihood of reoccurrence.
  - Majority of the time are related to lack of knowledge or expectations aren’t clear (policy).
Risk Assessment

- Why conduct a risk assessment?
- Four steps of the risk assessment process are:
  1. Identification
  2. Analysis and evaluation
  3. Prioritization
  4. Developing management risk-mitigation plans.
- Management ownership and buy in
- Audit and Monitoring Activities

Ongoing Improvement

Evaluating Effectiveness-done by third party for independence

To self assess how your compliance program is doing you can use several tools to document your progress:
- Program metrics (hotline calls, incidents, etc.)
- Surveys, Focus Groups
- Compliance self assessments/ risk assessment tools to evaluate risks from baseline identification
- Exit Interviews

Is program working as designed and implemented? Impact?