



# Effective Compliance Programs Are The Foundation

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# Key Learning Points

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How do you know if your Compliance Program is doing what it is intended to do?

# What Makes a Compliance Program Effective?

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## **Active support from the Top**

- Fiduciary duty of care
- Active and engaging Board of Directors
- Board resolution endorsing the Program
- Strong statement from the CEO in the Code of Conduct
- High level personnel assigned to oversee Compliance
- Adequate resources dedicated to the Medicare line of business
- Compliance is part of everyone's performance evaluation (including the CEO's and FDRs)

# Compliance Program: Two Basic Components

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- **Structural:**
  - Necessary to build and operate an effective Compliance program
    - Includes the minimum required seven elements
- **Substantive:**
  - Specific laws which the organization must comply with
    - Medicare
    - CMS Program requirements
    - OIG's Work Plan
    - Privacy and Security regulations

# Regulatory Background

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- Pursuant to revised regulations at 42 CFR §422.503 (b)(4)(vi) and 42 § CFR 504(b)(4)(vi) MA and Part D sponsors must:
  - Adopt and implement an **effective** compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse.
  - At a minimum must include the 7 core elements
- Regulations became effective June 7<sup>th</sup>, 2010
- Compliance program changes became effective January 1, 2011

# Expectations

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## What should be in place vs. what is in place

- Criteria – What should be
- Condition – What is
- Cause – Why the condition happened
- Effect – The difference and significance between *what is* and *what should be*
- Recommendation – Actions needed for correction
- **Effectiveness Measures**
  - Effort – the time, money, resources and commitment (Intent)
  - Outcomes – the impact that an organization's efforts has on its level of compliance (behavior)

# Common Deficiencies

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- Standards of conduct and Policies and Procedures
- Compliance Officer duties, reporting, and resources
- Compliance Committee meetings, minutes,
- Hotlines and other methods of communication
- Training and Education
- Senior Management and BOD oversight
- Prompt Response
- Internal Monitoring and Auditing
  - FWA as well as Operational compliance
- OIG LEIE and GSA Debarment
- FDR Oversight

# Culture of Compliance

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## Visible - Behavioral - Obvious

- Organization
  - Dedicated to doing the right thing always
  - The Chief Compliance officer is not the enemy
  - Compliance is business as usual
  - Compliance is the job, not an impediment to the job
- Employee
  - Know the rules applicable to the job
  - Ask if doesn't know
  - Speak up if have a concern
  - Do the right thing when no one is looking



# Effective?

## Element 1 – Written Policies and Standards of Conduct

- **Comply with all applicable Federal and State standards**
  - Does a code of conduct exist?
  - Does it explicitly state the commitment?
  - Clearly written, understandable?
  - Have been communicated and distributed to all?
  - Do all parties sign it?

# Effective?

## Element 1 – Written Policies and Standards of Conduct (cont.)

- **Expectations as embodied in the standards of conduct**
  - Do policies and procedures exist for relevant topics and areas?
  - Are policies created that explain and operationalize the commitment as stated in the code of conduct?
  - Periodically re-evaluated and updated?

# Effective?

## Element 1 – Written Policies and Standards of Conduct

- **The operations of the compliance program:**
  - Board resolution?
  - Has a risk assessment been completed to identify the relevant risk areas?
    - Regulations, sub-regulatory guidance (HPMS, manuals)
    - OIG Guidance (Annual Work Plans, special Fraud Alerts)
  - Have audits revealed fewer errors in areas where policies have been implemented?
  - Upon testing, are the internal controls established by policies working?

# Effective?

## Element 1 – Written Policies and Standards of Conduct

- **Provide guidance to others,**
  - Are policies understandable and capable of being fully applied?
  - Have the requirements of the policies and procedures been communicated to employees?
    - Readily available to employees, FDRs, etc.
    - Have any audits been conducted to monitor compliance with the policies and procedures?
    - Do employees understand what the policies require?
  - Identify how to communicate compliance issues to compliance personnel
  - Describe how compliance issues are investigated and resolved
- **A policy of non-intimidation and non-retaliation**

# Effective?

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## Element 2 - Compliance Officer and Compliance Committee

- **Must be an employee**
  - Is there a clear job description?
  - Are there sufficient resources ( personnel, funding, and systems) available?
  - Is there a compliance officer who is well qualified?
  - Competent, knowledgeable, Trustworthy, humble?
  - Visible, available, accessible, approachable?
  - Senior and not subordinate to Counsel or CFO
  - Mayor vs. Sheriff?
  - Authority?
  - Access to staff at all levels and across departments?
  - Who is supported by a Compliance Committee?

# Effective?

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## Element 2 - Compliance Officer and Compliance Committee

- **Is there an active compliance committee?**
  - Is there a Charter?
  - Trained representatives of each relevant functional departments?  
Members of senior management?
  - Are ad hoc groups or task forces utilized?
  - Meet regularly? Quarterly, monthly?
  - Serve as a resource to the Compliance Officer?
- **The compliance officer and committee must periodically report directly to the governing body**
  - Does the compliance officer have access to Governing body?
  - Does the compliance officer make regular report to the governing body?

# Effective?

## Element 2 - Compliance Officer and Compliance Committee

- **Knowledgeable about the compliance program and exercise reasonable oversight over the implementation and effectiveness of the program**
    - Is Board training provided?
    - Is there a Compliance Committee of the Board?
    - Does the Compliance Officer report to this Committee?
    - Does this Committee report to the Full Board?
- Not supervision  
Communications

# Effective?

## Element 3 - Training and Education

- **Between Compliance Officer and Several Key Groups**
  - At a minimum annually and at Orientation
  - Has the governing body been provided with appropriate training?
  - Are training and education activities well documented?
  - Are there attendance requirements?
  - Does the organization have qualified trainers?
  - Do the trainers:
    - Conduct annual compliance training?
    - Including general and specific training?  
Medicare Part C, D and Fraud, Waste, and Abuse
  - Is training evaluated for effectiveness?



# Effective?

## Element 3 - Training and Education

### Has the organization:

- Kept current on changes in Federal health care program requirements?
- Adopted training and education accordingly?
- Approve training materials and track completion of compliance & FWA training for FDRs (PBM, pharmacies, providers, etc.)
- Is education and training curriculum developed considering the following:
  - Results of audits and investigations?
  - Results of previous training and education activities?
  - Hotline reports received?
  - OIG/CMS communications?

# Effective?

## Element 4 - Lines of Communication

- **Lines of Communication are confidential, accessible, ...reporting is anonymous and in good faith**
- Has the organization fostered an organizational culture that:
  - Encourages open communication?  
Compliance concerns, potential misconduct, FWA questions
  - Prevents retaliation?
  - Maintains anonymity and confidentiality
- Hotline:
  - Has one been established?
  - Is it publicized? To All [FDRs, Beneficiaries, etc.]
  - Are calls logged and tracked for trends?
  - Do callers receive feedback?

# Effective?

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## Element 4 - Open Lines of Communication

- Do the necessary communication policies exist and have they been implemented and maintained?
- Are all potential fraud and abuse issues investigated?
- Are results of internal investigations routinely reported to governing body?
- Is the governing body actively engaged in pursuing appropriate remedies to institutional or recurring problems?
- Have employees been surveyed to evaluate their knowledge of the reporting mechanism?
- Does evidence show that there is a confidence in the reporting mechanism?
- Is analysis being conducted on reports to determine whether response is timely and thorough?

# Effective?

## Element 5 - Well Publicized Disciplinary Standards

- **Articulate expectations for reporting issues and their resolution**
  - Does the policy address enforcement of compliance standards and discipline of those who violate them?
  - Are employees and FDRs screened routinely against government sanction lists?
- **Identify noncompliance or unethical behavior**
  - Are enforcement and disciplinary standards communicated throughout the organization?
  - Is compliance an element of performance reviews and incentive compensation decisions?

# Effective?

## Element 5 - Well Publicized Disciplinary Standards

- **Timely, consistent, and effective enforcement**
  - Are disciplinary standards well publicized?
  - Consistently enforced and documented?
  - Timely?
  - A review of disciplinary actions taken as a result of compliance failures with CMS requirements and/or incidents of FWA:
    - Who, when, and how was it reported?
    - What was the incident?
    - What action was taken as a result?
    - When did the disciplinary action occur?

# Effective?

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## Element 6 - Internal Monitoring and Auditing

- **An effective system for routine monitoring**
  - Has a risk assessment of all program areas (including FWA) been conducted for the current operating year?
  - Is an annual audit plan developed that addresses risks to Part C and D benefits and monitors compliance with policies and procedures?
  - Is audit staff qualified and knowledgeable of Medicare program requirements?
  - Are audit staff objective and independent from the areas that they are auditing?
  - Use monitoring to help identify risk areas for further auditing?
  - Use risk assessment to guide the design of monitoring activities?

# Effective?

## Element 6 - Internal Monitoring and Auditing

- Does analysis of the results of repeat audits indicate an upward trend of improvement in the Org. understanding of and compliance with internal and external standards?
- Does the audit plan include evaluation of overall effectiveness of the compliance program?
- Does the organization have a written compliance auditing and monitoring plan that includes subject, method, and frequency of audits?
- If any major findings were made, was senior management and/or the Board notified as appropriate in a timely manner?
- When appropriate, have government agencies been notified of adverse finding in a timely manner?

# Effective?

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## Element 6 - Internal Monitoring and Auditing

- Have written corrective action plans been produced and followed when adverse findings were made?
- Are audit plans built on organizational history?
- Have audit results been disseminated to the appropriate groups for corrective actions?
- **FDR?**
  - How many are there? What function do they perform?
  - Is FDR oversight centralized or decentralized?
  - Who is responsible for oversight?
  - How do you measure compliance of FDR's performance with CMS requirements?



# Effective?

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## Element 7 - Prompt Response to Detected Offenses

- **Evidence of misconduct related to payment or delivery of items or services under the contract**
  - Process for promptly responding to potential issues of noncompliance? (detected offenses)
  - Are all thoroughly and promptly investigated?
- **Conduct appropriate corrective action**
  - Are corrective action plans developed?
  - Is corrective action taken verified after implementation?
  - Demonstrate that ongoing harm is halted promptly upon discovery of confirm non-compliance?
  - Do closed and ongoing investigations demonstrate promptly resolving reports of suspected non-compliance?

# Effective?

## Element 7 - Prompt Response to Detected Offenses

- Are corrective action responses to investigations consistent with legal requirements and with the recommendations of regulatory agencies?
- Do the organization's monitoring efforts indicate that preventative measures taken in response to non-compliance are effective in eliminating future instances of similar non-compliance
- **Procedures to voluntarily self-report potential fraud or misconduct**
  - Are the findings, status, and outcomes of internal investigations reported regularly to appropriate oversight and management bodies?

# Effective?

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## Element 7 - Prompt Response to Detected Offenses

- Do these bodies record their oversight of the organization's investigation, response and prevention activities in their respective minutes?
- Has the organization developed written policies or protocols for responding to requests, requirements or investigations?
  - Voluntary Disclosure
    - Federal Statutes – Duty to disclose
    - Deciding which Agency to disclose to

# Effective?

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## Preventing, Correcting, and Detecting FWA

- **Fraud, Waste, and Abuse Oversight**
  - Risk Assessments?
  - Oversight focus?
    - Sponsor, Providers, Beneficiaries, PBM
  - SIU department and responsibilities?
  - Monitoring, auditing, trending?
  - How do you measure that all are training to detect and report?
  - Oversight effective?
  - How do you know?

# Effective?

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## Preventing, Correcting, and Detecting FWA

- **Fraud, Waste, and Abuse:**
  - Detection and Prevention
  - Training, i.e.
    - Definitions
    - What fraud looks like
  - Bi-directional inspections
    - Inside for potential misuse or abuse
    - Outside for fraud, waste, and abuse
  - Most states require health plans to have Fraud, Waste, and Abuse Plans
  - Many require plans to have Special Investigation Units

# Effective?

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## Preventing, Correcting and Detecting FWA

- **Fraud, Waste, and Abuse:**
  - Consistent message from all departments is often a challenge.
  - Each department has an agenda
    - Credentialing
    - Quality Management
    - Network Management
    - Claims
    - Compliance or the SIU
    - PBM
  - How does the organization ensure the message is the same? That's the test of their "effectiveness."
  - Checking employees and vendors against the LEIE and GSA Excluded Parties lists on a frequent basis

# Effectiveness?

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- **Effective does not equal:**
  - Expensive
  - Expansive
  - Experimental
  
- **Effective does mean:**
  - You are doing what you say you will do
  - Compliance is a part of every employee's job description
  - Measurement & Metrics—You know it's working?