

# **Connecting the Dots**

*A Practical Approach to Integrating Compliance,  
Risk and Quality*

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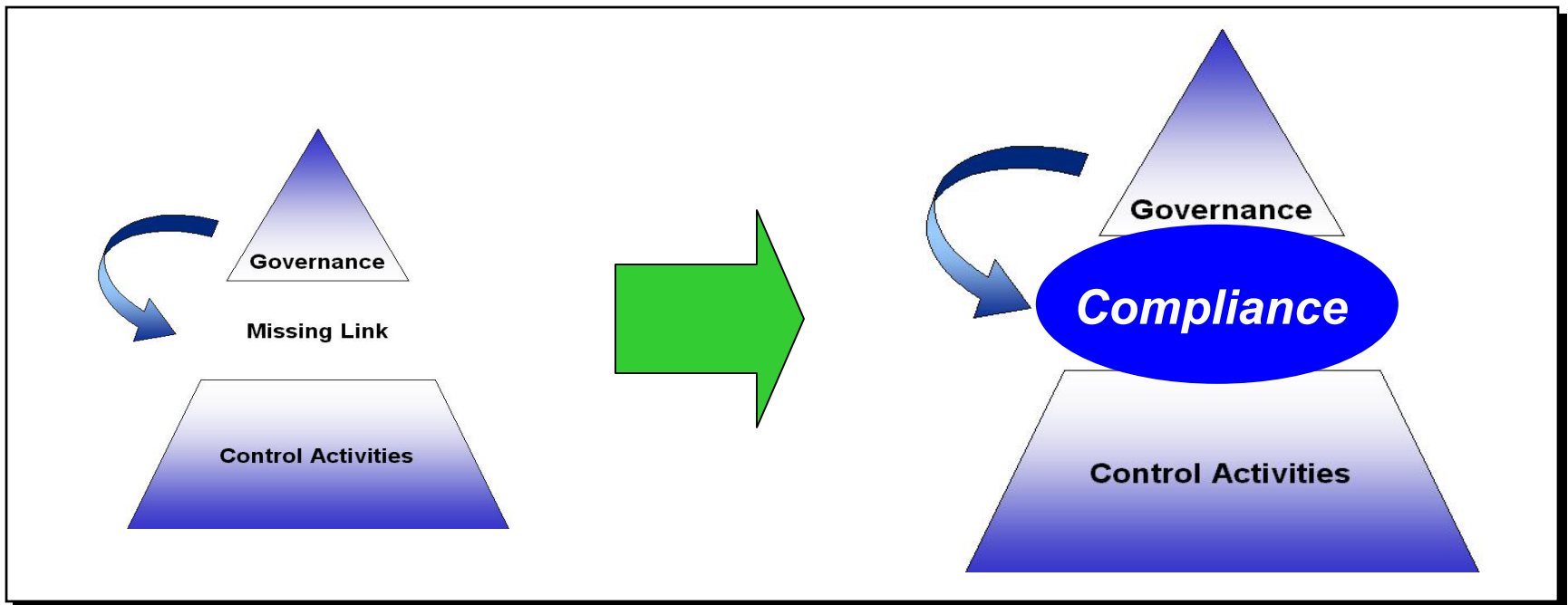
**Partner**

**Health Care Regulatory Practice**

# The Role of Compliance

The effectiveness of Senior Management's oversight is typically limited because:

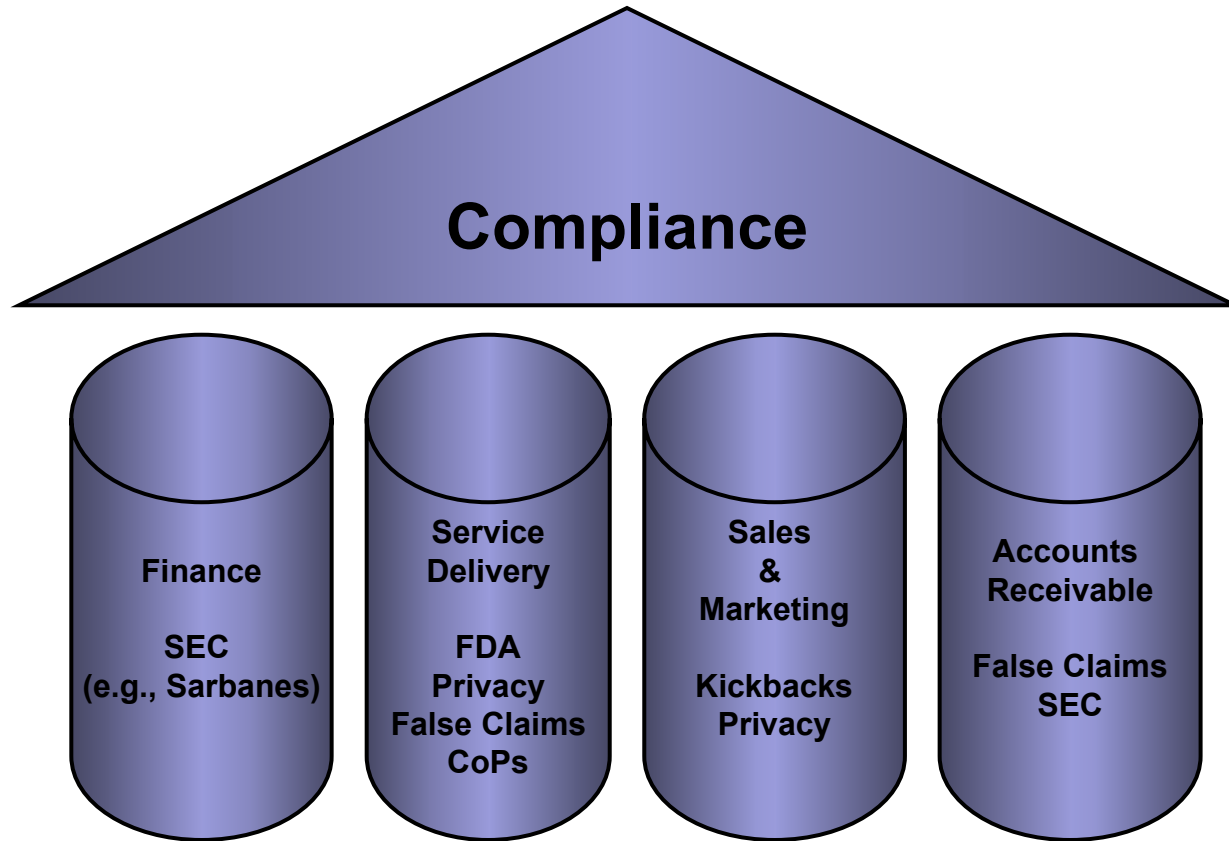
- Limited linkage between governance and control activities
- Existing internal control structures do not address the full range of risks
- Key risks are managed by separate groups (e.g., FDA compliance, clinical trials, manufacturing quality)



The “missing link” is a **compliance program and infrastructure** to measure and monitor the effectiveness and alignment between corporate governance and business unit / functional risk management, compliance and quality activities.

# Traditional Model

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**Quality, compliance and business risks managed by silo -  
difficult to track all of the moving parts**

# Emerging Model

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**Quality, compliance and business risks managed in a coordinated manner -  
easier to see key interrelationships and interdependencies**

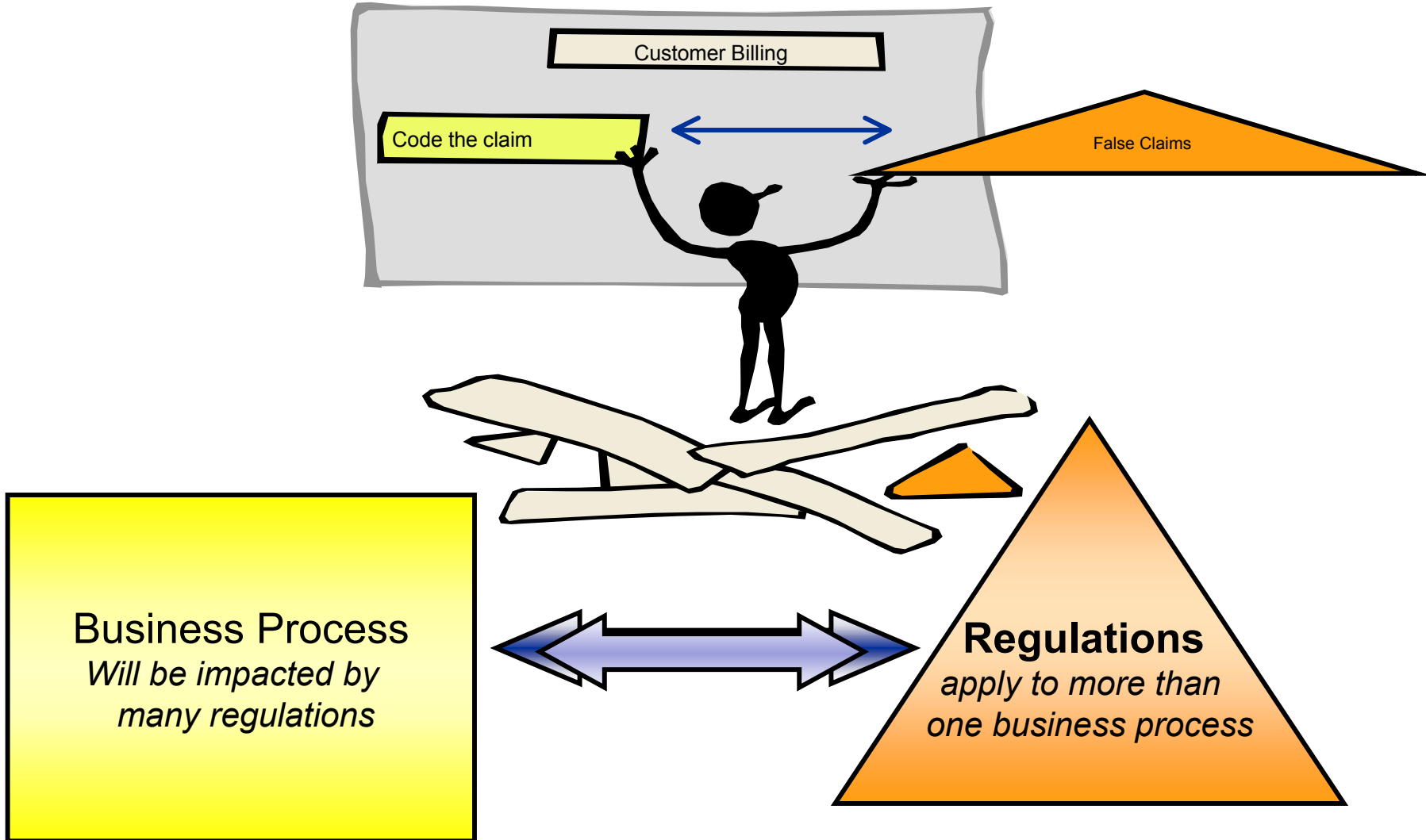
# The Compliance Program Design Dilemma

- Compliance-related risks touch every aspect of the organization's business & are difficult to “compartmentalize”
- The design should be based upon the organization's business structure
- The design should result in a set of organization-wide compliance processes

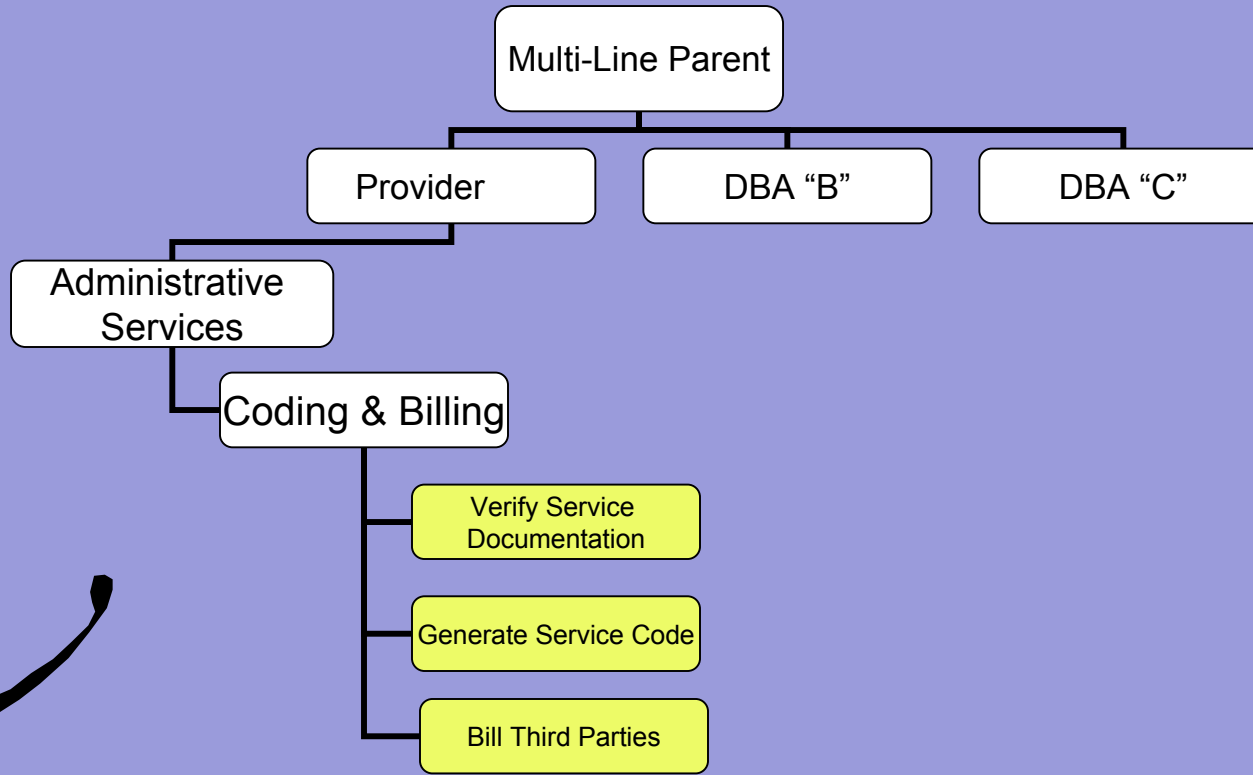


# The Compliance Program Design Solution . . .

## . . . Create a Compliance “Crosswalk”



# Step One: Characterize the organization's business structure



# Step Two: Establish the Standards for Each Risk Area

## ■ Define the risk areas

- Financial
- Regulatory
- Systems/IT
- Operational

## ■ Define the standards

- The criteria for compliance
- Groupings for Score Card purposes

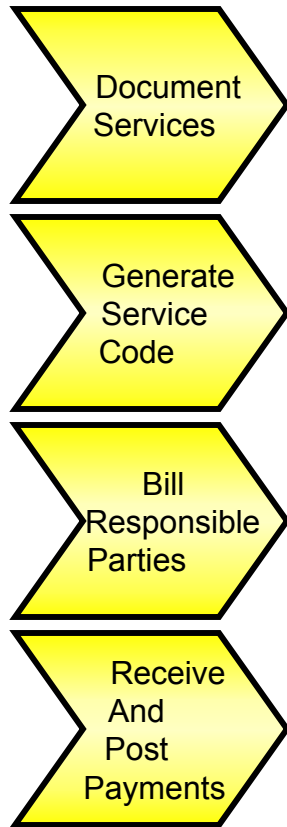
## ■ Cite the authority

- Helpful to identify the source
- Allows for translation
  - Standard to Operations
  - Operations to Standards

Standard No.	Standards	Authority
Inducements	Has the organization defined and documented those items or services that are reimbursable by Federal Health Care programs?	
	Has the organization identified, documented and tracked customers who buy items or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that prohibit <u>payments</u> to induce or reward sales or leases of the organization's products or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that prohibit the <u>use of gifts or other items of value</u> to induce or reward sales or lease of the organization's products or services that are reimbursable by Federal Health Care Programs?	
	Are policies and procedures documented and implemented that prohibit <u>offers</u> of anything of value to induce or reward sales or leases of the organization's products or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that prohibit <u>arranging for the sale or lease</u> of the organization's goods or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that prohibit <u>offers of anything of value to induce or reward a person or entity that arranges for the sale or lease of the organization's products or services that are reimbursable</u> by Federal Health Care programs?	
	Are policies and procedures documented and implemented that establish requirements for offering price concessions to customers who purchase items or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that establish requirements for offering price concessions to wholesalers?	67 Fed Reg 62057, 62061
	Are policies and procedures documented and implemented that establish requirements for offering price concessions to Group Purchasing Organizations, Pharmacy Benefit Managers or other entities that are in a position to influence the purchase of the organization's items or services?	67 Fed Reg 62057, 62061
Discounts	Are policies and procedures documented and implemented that establish the contractual requirements for discounts when the purchaser purchases items or services that are reimbursable by Federal Health Care programs?	42 CFR 1001.952(h)
	Do policies and procedures require the organization to inform its customers of any discounts that have been provided and the customer's reporting obligations?	
	Do policies and procedures prohibit the organization's employees from impeding a customer's ability to meet its discount reporting obligations?	
	Do policies and procedures set forth standards to apportion discounts or other terms of sale that may impact the price for items or services that are reimbursable by Federal Health Care programs?	
Personal Services Agreements	Are policies and procedures documented and implemented that establish requirements for professional services contracts with individuals or entities that provide services to the organization?	
	Has the organization documented and tracked all of the individuals or entities that provide professional services to the organization?	

# Step Three: Create the crosswalk

## Coding & Billing



Standard No.	Standards	Authority
Inducements	Has the organization defined and documented those items or services that are reimbursable by Federal Health Care programs?	
	Has the organization identified, documented and tracked customers who buy items or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that prohibit <u>payments</u> to induce or reward sales or leases of the organization's products or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that prohibit the <u>use of gifts or other items of value</u> to induce or reward sales or lease of the organization's products or services that are reimbursable by Federal Health Care Programs?	
	Are policies and procedures documented and implemented that prohibit <u>offers</u> of anything of value to induce or reward sales or leases of the organization's products or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that prohibit <u>payments</u> in exchange for a person or entity's <u>arranging for the sale or lease</u> of the organization's goods or services that are reimbursable by Federal Health Care programs?	
	Are policies and procedures documented and implemented that prohibit <u>offers</u> of anything of value to induce or reward <u>a person or entity that arranges for the sale or lease of the organization's products or services that are reimbursable</u> by Federal Health Care programs?	
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Identify the compliance risks associated with each department and business process

## Step Four: Create a uniform process for review

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### ■ Frequency of reviews

### ■ Scope of the review

- Are their policies and procedures for the standard?
- Have employees been trained on the policies and procedures?
- Is there evidence that the policies and procedures are being followed?
  - Are employees aware of them?
  - Perform audits of certain requirements to evaluate compliance

# Step Five: Establish a Uniform Metric

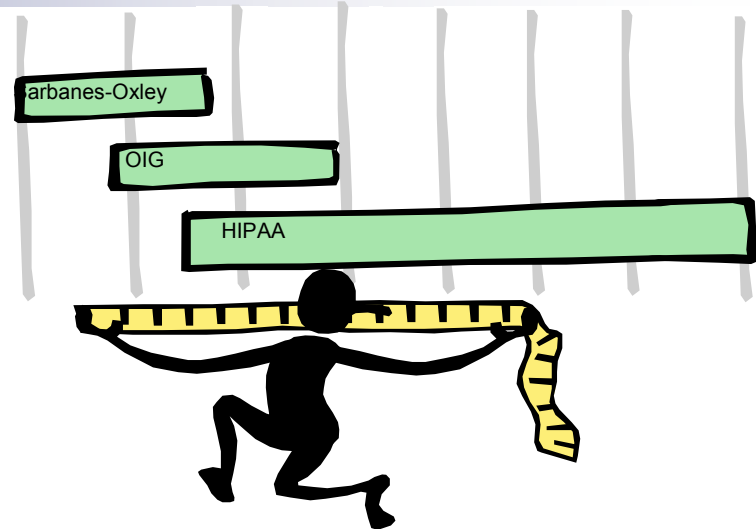
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## ■ How is compliance evaluated?

- Points?
- Stoplights?









## ■ What criteria will be used to “score” the finding?

- Presence of policies
- Presence of SOPs
- Employee Education
- Employee Awareness
- Formal Audits of documentation














# Step Six: Develop the Report Card

## By Department

	<u>Privacy</u>	<u>Inducements</u>
Admissions		
Customer Service		
Marketing		
Medical Records		

## By Risk Area

	<u>Privacy</u>
Privacy Notice	
Employee Training	
Complaints	
Employee Discipline	
Authorizations	
Minimum Necessary	
Access to Records	
Amendment of Records	
Confidential Communications	
Facility Directory	
Business Associate Agreements	

This allows the organization to identify areas of overlap and areas upon which to focus its efforts

# The Compliance Documentation Process

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- **Standards**
  - Each area of risk has a defined set of standards
- **Gap Assessment**
  - Policies and SOPs are compared to the standards
  - Implementation of policies and SOPs is assessed via observation, surveys, focus groups and interviews
- **Findings**
  - The standards are summarized in a Score Card or Status Board
  - The findings following a review are summarized on a dashboard
  - The Findings can be placed into a database or knowledge management system for easy reference and reporting
- **Corrective Action Plans**
  - Allow for documentation of specific findings
- **Ongoing Audit Protocol**
  - Utilize the baseline assessment to establish audit metrics and protocol

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The Key to  
Compliance is . . .



. . . Taking reasonable steps to comply with the regulations.  
Reasonable compliance can be demonstrated through a  
thoughtful and well-organized compliance program.