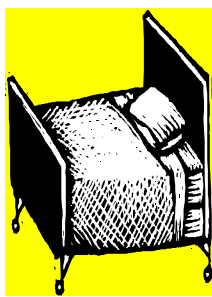




Compliance as Risk Management (and Vice Versa)



Fifth Annual National Congress on Health
Care Compliance

February 6 - 8, 2002

Grand Hyatt Hotel, Washington, D.C.



William M. Altman

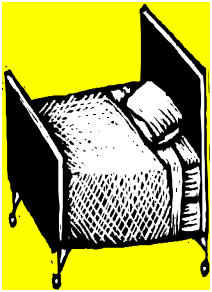
**Vice President of Compliance and Government Programs
Kindred Health Care**

David B. Orbuch

**Executive Vice President, Ethics and Compliance
Allina Hospitals and Clinics**



Overview of Presentation



I. Understanding Compliance as Risk Management and Vice Versa

II. Review Four-Step Framework for Evaluating Compliance Program Effectiveness

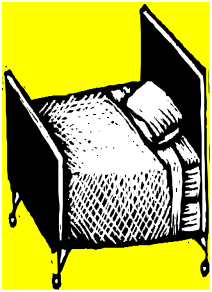
III. Discuss Practical Example of How This Framework Can Be Used as a Risk Management Tool

IV. Conclusion

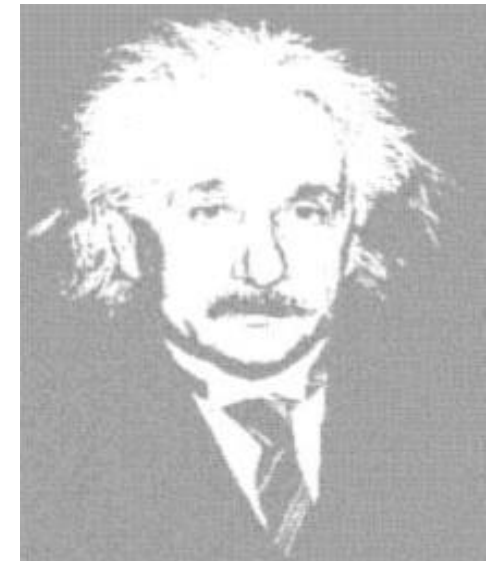
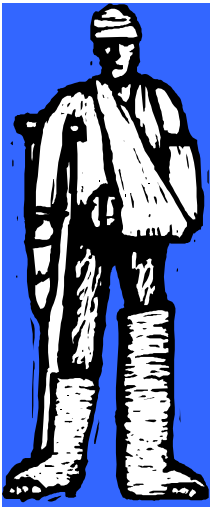




“The significant problems we face cannot be solved at the same level of thinking we were at when we created them.”

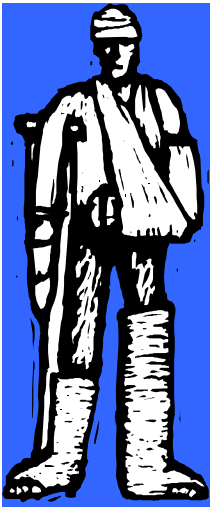
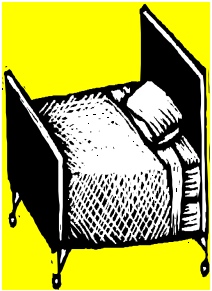


-- Albert Einstein





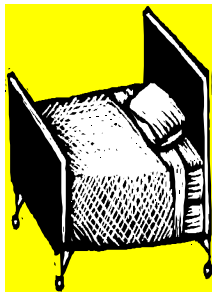
Dealing with Risk



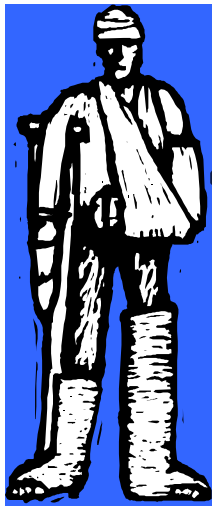
- Risk is encountered by everyone on a daily basis
- Controlling risk has always been important in the industrial work force
- Webster defines risk as:
 - Possibility of loss or injury
 - Dangerous element
 - Degree of probability of loss



Understanding the Meaning of Risk as It Applies to Risk Management

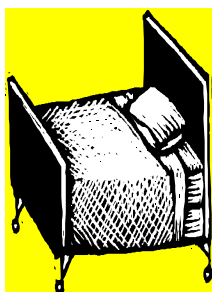


- Risk management is a management function aimed at the identification, evaluation and treatment of risks that could result in a loss
- The goal of risk management is to create an awareness of possible risks that represent financial threats or that are potentially harmful to stakeholders





Understanding the Meaning of Risk As It Applies to Risk Management (cont.)



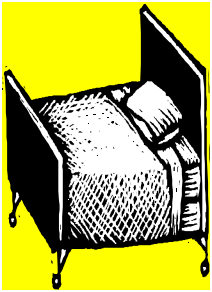
- Risk management has been traditionally an administrative undertaking intended to protect the financial assets of a health care provider in three ways:



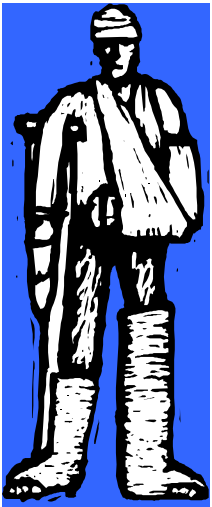
- by assuring adequate, appropriate insurance coverage against potential liability;
- by reducing liability when untoward events do occur; and
- by preventing those events that are most likely to lead to liability



Understanding the Meaning of Risk as It Applies to Risk Management (cont.)



- **Although risk management activities have always taken place in hospitals, it is only during the past 15 years that it has been recognized as a function**
 - 1965 case found that hospital (rather than physicians) directly responsible for patient care (Darling)
 - Medical malpractice crisis of the mid 70's expedited the development





Understanding the Meaning of Risk as It Applies to Risk Management (cont.)



- Hospitals were forced to find alternative methods of financing professional risk liability
- insurers required the establishment of a monitoring and evaluation system to identify physicians whose technique, judgment or motivation was less than optimal
- December 1988 the Joint Commission approved risk management-related accreditation standards



Understanding Risk as It Applies to Compliance

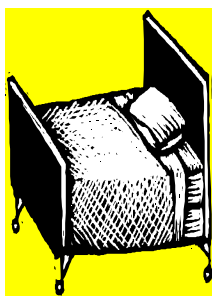


- A compliance program is a management function aimed at the identification, evaluation and treatment of risks that could result in a loss
- The goal of compliance is to create an awareness of possible risks that represent financial threats or that are potentially harmful to stakeholders





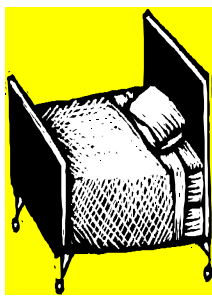
Understanding Risk as It Applies to Compliance (cont.)



- **At a basic level compliance is a system of policies and procedures developed to assure compliance with and conformity to all applicable state and federal laws governing the organization**
- **Coverage can be very broad**
- **Corporate compliance was born after November 1, 1991**



Understanding Risk as It Applies to Compliance (cont.)



- **The guidelines specifically provide that an offending organization may be given credit for the existence of an effective compliance program**
- **First corporate death sentence used in May of 1994 against American Precision Components, Inc. (if an organization is operated primarily for criminal purpose the fine shall be set at an amount sufficient to divest the organization of all its net assets)**





Understanding Risk as It Applies to Compliance (cont.)

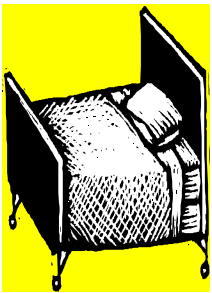


- **Increase in health care fraud prosecution after the amendment of the civil False Claims Act in 1986**
- **GAO study finding that 10% of the health care dollar spent reimbursing fraudulent behavior**
- **Huge national settlements (National Medical Enterprises (1994) - \$379 million with corporate integrity agreement; Allied Clinical Lab (1995) - \$4.9 million with corporate integrity agreement; Caremark (1995) - \$161 million with corporate integrity agreement)**

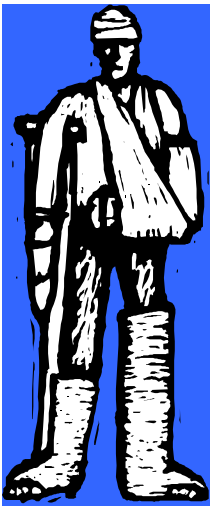
Understanding Risk as It Applies to Compliance (cont.)



- **Shareholder derivative lawsuit in Caremark (1996)**



- Directors have a duty to assure that corporate information gathering and reporting systems exist that are reasonably designed to provide board with time and accurate information sufficient to allow them to reach informed judgments concerning the corporation's compliance with applicable laws.



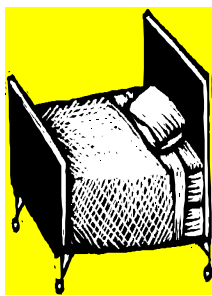
- **Corporate Compliance Guidance from HHS-OIG**

Hospitals - February 1998

Labs - August 1998



Why is Demonstrating Effectiveness Important?



- **U.S. Sentencing Guidelines**
- **OIG Compliance Program Guidance**
- **Qui Tam Actions/False Claim Prosecutions**
- **Justify Financial Resources Committed by Providers to Compliance**
- **Restore Public Trust of Health Care Providers**



What Do We Know Today About Compliance Program Effectiveness and How to Evaluate It?



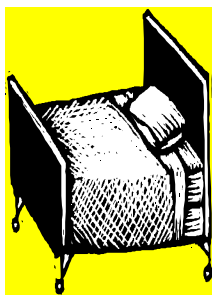
- **GAO Study (1999)**

- Evidence of effectiveness inconclusive
- Primary effectiveness measure was “ability to prevent improper Medicare payments:
- Other possible measures include amount/frequency refunded overpayments; frequency of self-disclosures





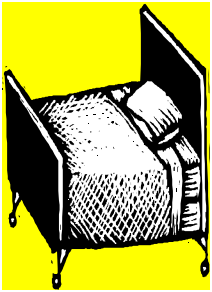
What Do We Know Today? (cont.)



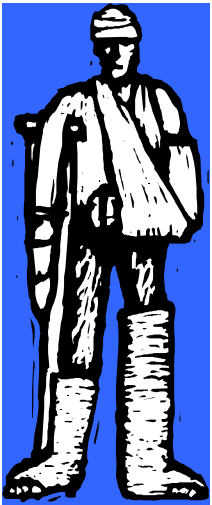
- **OIG Nursing Facility Compliance Guidance**
- **June Gibbs Brown, U.S. Department of Health and Human Services Inspector General, stated:**
 - “The existence of an effective compliance plan provides evidence that any mistakes were inadvertent, and this evidence would be considered in determining whether a medical practice or health care entity has made reasonable efforts to avoid and detect misbehavior.”



What Do We Know Today? (cont.)

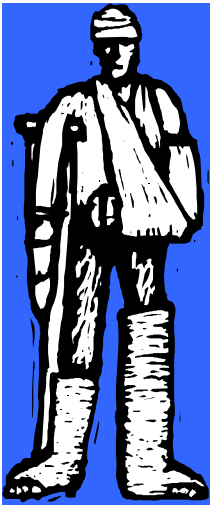
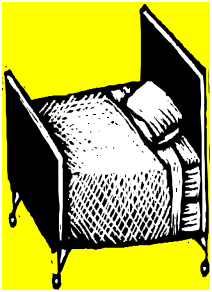


- **PwC / UCLA Study**
- **HCCA / Government Task Force**
- **Provider Efforts**





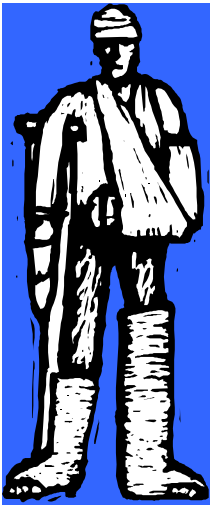
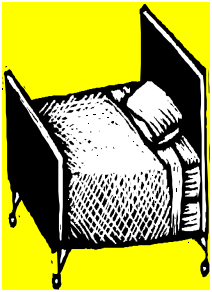
Shortcomings of Current Effectiveness Measurement Efforts



- **Failure to identify a framework for evaluating effectiveness**
 - Who is evaluating effectiveness?
 - What is the purpose?
- **Undue reliance on “outcome” measures**
- **Failure to account for the “maturity” of compliance programs or the regulatory context when evaluating effectiveness**



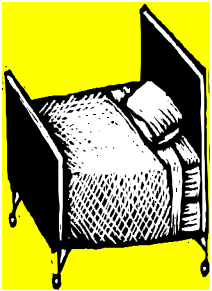
Four-Step Approach for Developing Effectiveness Measures



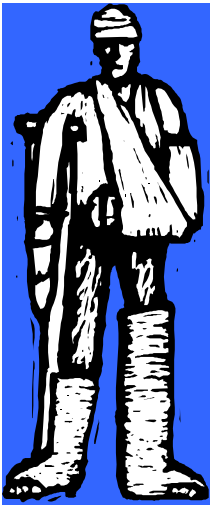
- **Step 1: Identify Stakeholders**
- **Step 2: Identify the Purpose and Context for evaluating effectiveness**
- **Step 3: Identify the Standards against which effectiveness will be measured**
- **Step 4: Select effectiveness Measures**



Step 1: Identify Stakeholders

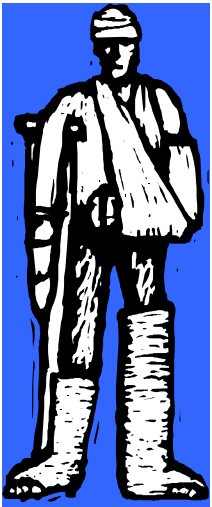
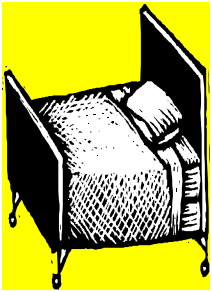


- **Law Enforcement (e.g., Justice Dept., FSC)**
- **Regulators (e.g., OIG)**
- **Provider Management**





Step 2: Identify Purpose/ Context



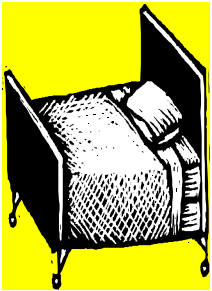
- **Law Enforcement Purpose**
 - Evaluate “intent” to obey law
 - Make prosecute / no-prosecute decision
- **Regulators**
 - Evaluate program participation status
 - Define terms / conditions of continued program participation
- **Provider Management**
 - Evaluate utility of compliance program as “risk management” tool
 - Determine whether money well spent on compliance



Step 3: Identify Standards

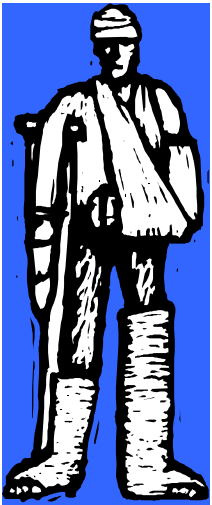
- **Law Enforcement**

- Purpose: Intent
- Standard: “Effort” or “Due Diligence”



- **Regulators**

- Purpose: Future program participation
- Standard: “Integrity” or “Capacity” for future compliance



- **Provider Management**

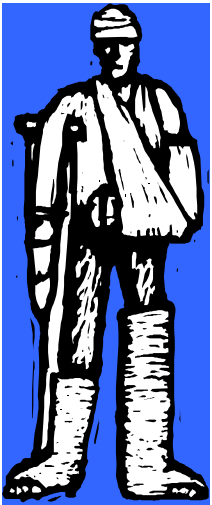
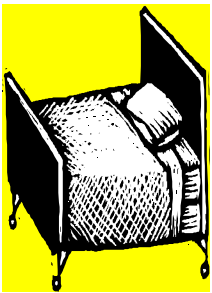
- Purpose: Compliance as risk management
- Standard: Cost-effectiveness



Step 4: Select Measures

- **Structure Measures**

- **Compliance Program Committee(s)**
- **Independent Compliance Officer**
- **Existence of Hotline**
- **Code of Conduct**
- **Policies and Procedures**
- **Overall Program Budget**

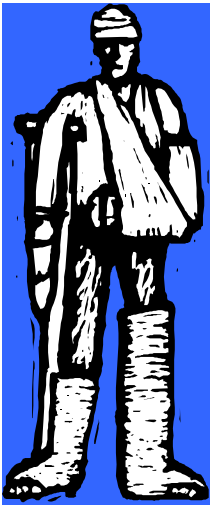
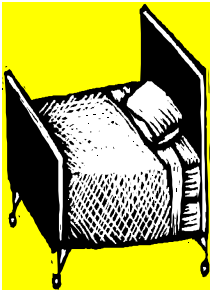




Step 4: Select Measures (cont.)

● Process Measures

- Education / training on compliance risk areas
- Ongoing monitoring mechanisms
- Audit processes
- Ability / inclination to respond to problems

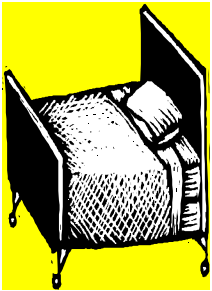




Step 4: Select Measures (cont.)

- **Outcome measures**

- Audit results
- Hotline calls / actions (high or low?)
- Disciplinary actions (high or low?)
- Overpayments (high or low)
- Quality of care clinical measures

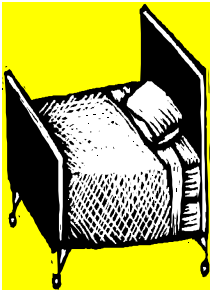




Step 4: Select Measures (cont.)

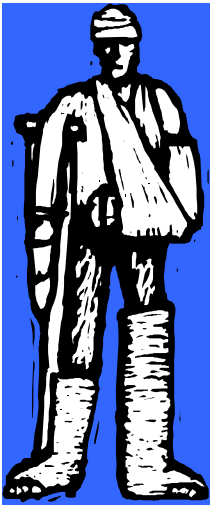
- **Law Enforcement**

- Purpose: Intent
- Standard: “Effort or “Due Diligence”
- Key Measures: Structure and Process



- **Regulators**

- Purpose: Future program participation
- Standard: “Integrity” or “Capacity” for future compliance
- Measures: Structure and Process



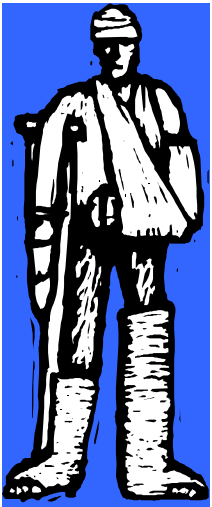
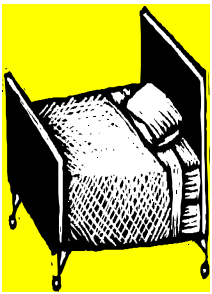
- **Provider Management**

- Purpose: Compliance as risk management
- Standard: Cost-effectiveness
- Measures: Outcome



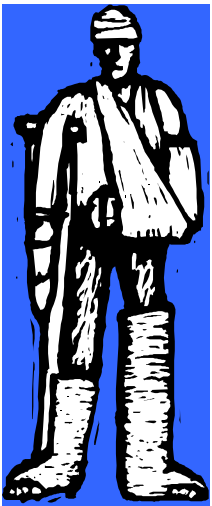
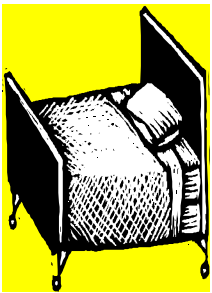
Key Points

- **Structure, process and outcome measures are all important**
- **Linkages between structure, process and outcome measures are most important**
- **When evaluating effectiveness, different measures may be appropriate at different points in time**
 - new compliance program
 - new regulations
 - unclear regulations
- **It is critical to identify the stakeholder, purpose and standard before adopting effectiveness measures**





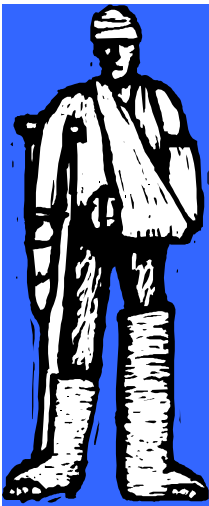
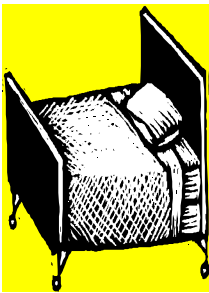
Compliance Scorecard



- **A practical risk management tool**
- **Useful in complex organizations to standardize evaluations**
- **Must be supported by upper management**
- **Can be used as performance evaluation tool**
- **Elements should change with progress of program**



Quarterly Compliance Scorecard -- ____ Quarter 2001



Date:		Hospitals	Clinics	Transportation	Homecare
Compliance Structure:					
New Employee Education	Y/N				
Ongoing Compliance Education	Y/N				
Standards and Procedures	Y/N				
Program Oversight	Y/N				
Effective Reporting Mechanism	Y/N				
Compliance Process:					
Corrective Action Plans Timely Filed	Y/N				
Corrective Action Plans Timely Completed	Y/N				
Ongoing Monitoring Shows Improvement	Y/N				
Key Compliance Indicators Being Monitored	Y/N				
Demonstration of Compliance Education Effectiveness	Y/N				
Compliance Outcome:					
Compliance Audit Error Rate (Most Recent Audit Results)					
Total Score x 5					
Rating					

Evaluation Key	
Green	80 and above
Yellow	60 and above
Red	59 and below



Conclusion

- **Compliance and risk management functions in health care organizations should, at a minimum, be coordinated**
- **Focus of compliance should be risk management**
- **To be effective, both disciplines must be an ongoing process, a part of the organization's fabric**
- **Both are based on the value of stewardship**

