

# Risk Management Mentor Program

# Program Disclaimer

## ► Modules

1. Risk Management Fundamentals
2. Enterprise Risk Management
3. Applications
4. Healthcare Providers
5. Clinical and Patient Safety
6. Legal and Regulatory
7. Claims and Litigation
8. Risk Financing

## ► Topics

- Web links
  - Primary sources
  - Templates
  - Questions
  - Responses



# **Module 6**

## **Legal and Regulatory**

## ► Objectives

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Identify components of a valid contract

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Identify three authorized uses of protected health information

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Explain the seven elements of a effective corporate compliance plan

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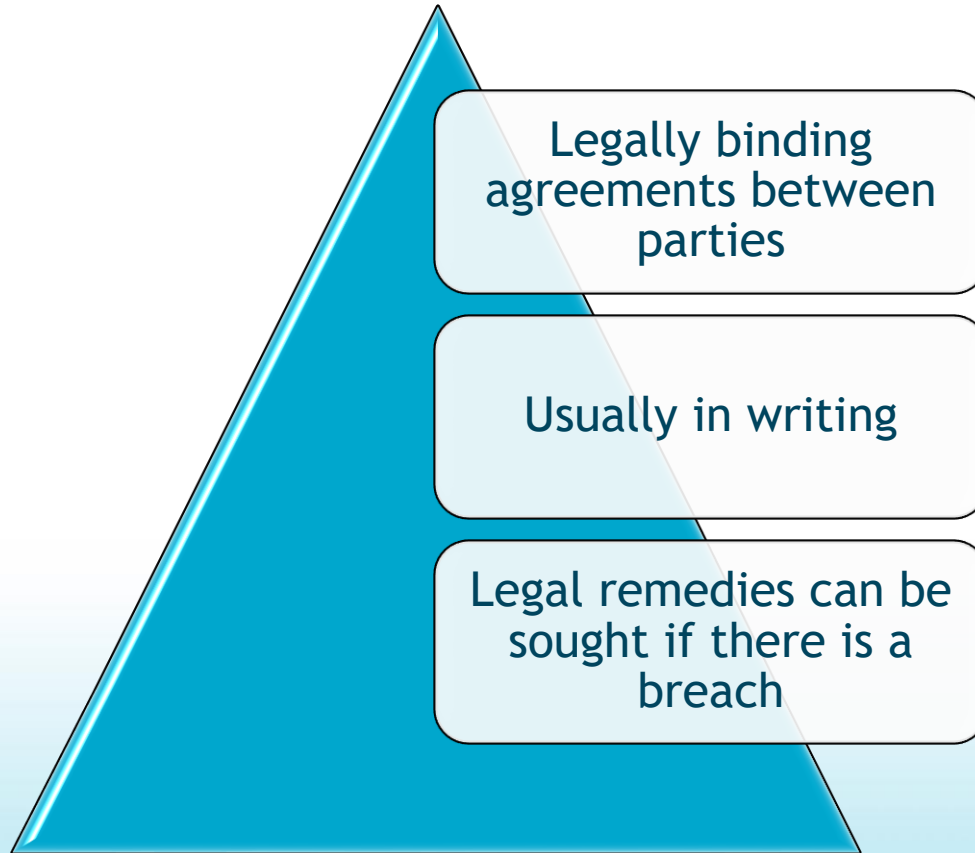
Discuss the role of the Occupational Safety and Health Administration, the Centers for Medicare & Medicaid Services, and the Food and Drug Administration

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Identify the various accreditation bodies

# Contracts

# ▶ Contracts





## ► Legal aspects of a contract

- Offer and acceptance
  - Legal capacity
- Consideration
- Something of value exchanged
- Legal purpose of the agreement
- Mutual agreement
  - “A meeting of the minds”



## ► Components of written contract

Introductory  
statements  
“recitals”

Definitions of  
key terms

Statement of  
purpose(s) of  
agreement

Obligations  
of each party

Warranties

Other  
boilerplate  
provisions

## ► Types of contracts

Insurance

Vendors

Managed care

Construction

Business auto

Equipment maintenance

Student/affiliations/staffing

## ► Contract file management

### Contract files

- File names
- Include party names, time period, and anniversary date

### Tickler system

- Review contract before anniversary
- Dates: anniversary, termination and notice requirement

## ▶ Contract review checklist



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Identifiable effective dates

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Parties to contract identified

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Limits appropriate

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Mutual indemnification clause

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Full description of obligations

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Governing state law

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Termination terms

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Reference documents attached

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# Health Insurance Portability and Accountability Act (HIPAA)

# ▶ Health Insurance Portability and Accountability Act



The Health Insurance Portability and Accountability Act (HIPAA) provides protection for protected health information (PHI) held by covered entities (CEs) and their business associates (BAs)



The regulations include:

- The Privacy Rule
- The Security Rule
- The Breach Notification Rule



## ► HIPAA basics

Protected health information (PHI) can be used for treatment, payment, and operations

Patients have certain rights

Covered entity (CE) must maintain physical, technical, and administrative safeguards

Office of Civil Rights (OCR) can impose penalties



## ► Case examples from HHS.gov

Pharmacy maintained pseudoephedrine log book that contained patient information at the pharmacy counter

A medical office staff member discussed HIV test procedures with a patient in the waiting room

## ► Case examples from HHS.gov

A hospital employee left a telephone message with the daughter of a patient that detailed her medical condition and treatment plan



A mental health center did not provide a Notice of Privacy Practices (notice) to a patient



## ► HIPAA resources

- [Guide to Privacy and Security of Health Information](#) (The Office of the National Coordinator for Health Information Technology)
- [Health Information Privacy](#) (U.S. Department of Health and Human Services)
- [HIPAA Frequently Asked Questions for Professionals](#) (U.S. Department of Health and Human Services)
- [HIPAA Privacy and Security Essentials](#) webinar (MedPro Group)
- [HIPAA Security Risk Analysis Toolkit](#) (Medical Group Management Association)
- [HIPAA Security Rule: Frequently Asked Questions Regarding Encryption of Personal Health Information](#) (American Medical Association)
- [Individuals' Right Under HIPAA to Access Their Health Information 45 CFR § 164.524](#) (U.S. Department of Health and Human Services)
- [Responding to Legal Requests and Demands for Protected Health Information presentation](#) (MedPro Group)

# Occupational Safety and Health Administration (OSHA)

# ▶ Occupational Safety and Health Administration

- ▶ Ensures safe and healthful working conditions for employees
  - ▶ Set and enforce standards
  - ▶ Training, outreach, and education
- ▶ Standards explicitly require employers to train employees in the safety and health aspects of their jobs
- ▶ Standards state that employers must protect employees from hazards
- ▶ Officials can conduct unannounced inspections
- ▶ Priorities for inspection are imminent danger, catastrophes, worker complaints, referrals, and targeted inspections

## ► Employer responsibilities



Provide required personal protective equipment

Record work-related injuries and illnesses

Post OSHA citations, summary data, and Job Safety and Health poster

No retaliation against any worker law

## ► Employer responsibilities



Follow OSHA safety and health standards

Find and correct safety and health hazards

Inform employees about chemical hazards

Notify OSHA of workplace fatality or hospitalization

## ► Other requirements

General Duty Clause of the OSHA Act of 1970

Employers must keep their workplaces free of serious recognized hazards.





U.S. Department of Labor

May 2, 2018

## **U.S. Department of Labor Cites Florida Health Facility for Exposing Employees to Workplace Violence**

**BRADENTON, FL** – The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) has cited Premier Behavioral Health Solutions of Florida Inc. and UHS of Delaware Inc., the operators of Bradenton-based Suncoast Behavioral Health Center, for failing to protect employees from violence in the workplace. Proposed penalties total \$71,137.

OSHA responded to a complaint that employees were not adequately protected from violent mental health patients. OSHA [cited](#) Premier Behavioral Health Solutions of Florida Inc. and UHS of Delaware Inc., subsidiaries of Universal Health Services Inc., for failing to institute controls to prevent patients from verbal and physical threats of assault, including punches, kicks, and bites; and from using objects as weapons. Another UHS subsidiary was cited in 2016 for a deficient workplace violence program.

"This citation reflects a failure to effectively address numerous incidents over the past two years resulting in serious injuries to employees of the facility," said Les Grove, OSHA Tampa Area Office Director.

Premier Behavioral Health Solutions of Florida Inc. and UHS of Delaware Inc. have 15 business days from receipt of its citations and proposed penalties to comply, request an informal conference with OSHA's area director, or contest the findings before the independent [Occupational Safety and Health Review Commission](#).

Under the Occupational Safety and Health Act of 1970, employers are responsible for providing safe and healthful workplaces for their employees. OSHA's role is to ensure these conditions for America's working men and women by setting and enforcing standards, and providing training, education, and assistance. For more information, visit <http://www.osha.gov>.

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## ► Employee rights

Get test results  
regarding hazards  
in the workplace

Work in  
conditions that do  
not pose a risk of  
serious harm

Receive  
information and  
training

## ► Employee rights

File a  
complaint

Use employee  
rights under the  
law without  
retaliation

Review records  
of work-related  
injuries and  
illnesses

## ▶ **OSHA resources**

- ▶ OSHA website
- ▶ Industry-specific Resources
- ▶ Training Requirements and Resources
- ▶ Recommended Practices for Safety and Health Programs

# Centers for Medicare & Medicaid Services (CMS)

# ▶ Centers for Medicare & Medicaid Services

- ▶ Oversees these federal healthcare programs:
  - ▶ Medicare
  - ▶ Medicaid
  - ▶ Children's Health Insurance Program
- ▶ Other responsibilities:
  - ▶ The administrative simplification standards from HIPAA
  - ▶ Quality standards in long-term care facilities and clinical laboratories
  - ▶ Oversight of HealthCare.gov
- ▶ The Medicare Learning Network provides free educational materials

## ► Conditions of coverage and conditions of participation

- Conditions of participation (CoPs) and conditions for coverage (CfCs) are health and safety standards that healthcare organizations must meet.
- These conditions improve the quality and protect the health and safety of beneficiaries.
- CMS ensures that standards of accrediting organizations meet or exceed standards set forth in the CoPs/CfCs.
- The conditions apply to a variety of organizations.

## ▶ CMS resources

- ▶ [CMS website](#)
- ▶ [CMSHHSgov. YouTube](#)
- ▶ [Conditions for Coverage \(CfCs\) & Conditions of Participation \(CoPs\)](#)



# Food and Drug Administration (FDA)

## ► Food and Drug Administration

Ensures safety of human and veterinary drugs, biological products, and medical devices

Regulates manufacturing, marketing, and distribution of tobacco products

Aids in counterterrorism efforts

## ► What the FDA regulates

Food

Prescription  
and non-  
prescription  
drugs

Biologics

Medical  
devices

## ► What the FDA regulates

Electronic  
products  
emitting  
radiation

Cosmetics

Veterinary  
products

Tobacco  
products

# ► Medical device reporting



- Manufacturers, device user facilities, and importers must submit reports of adverse events and problems
- Healthcare professionals and consumers encouraged to report
- Device user facilities must report a device-related death or serious injury to FDA and/or manufacturer
- User facilities must develop, implement, and maintain written procedures and maintain medical device reporting files
- FDA has criminal and civil penalty authority

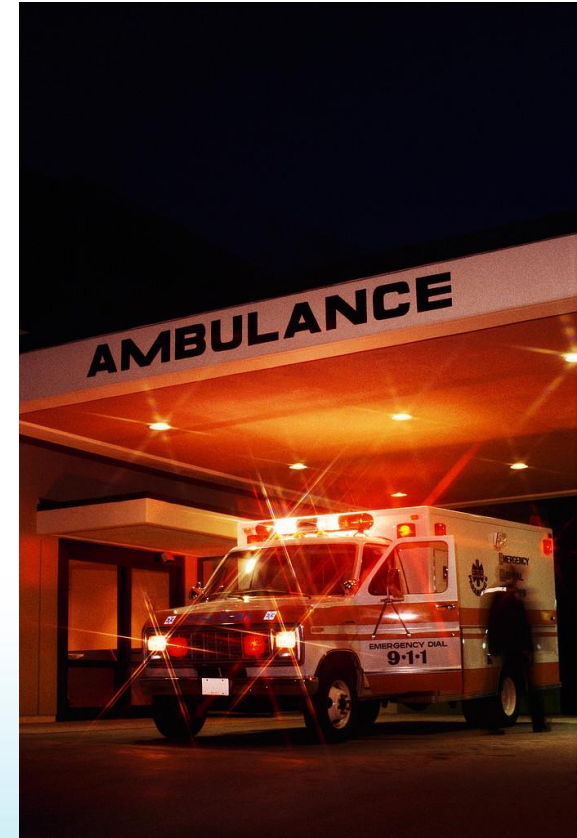
## ▶ **FDA resources**

- ▶ [FDA website](#)
- ▶ [Enforcement Reports](#) (information about product recalls and other enforcement actions)
- ▶ [Recalls, Market Withdrawals, and Safety Alerts](#)
- ▶ [Medical Device Safety](#)

# Emergency Medical Treatment and Labor Act (EMTALA)

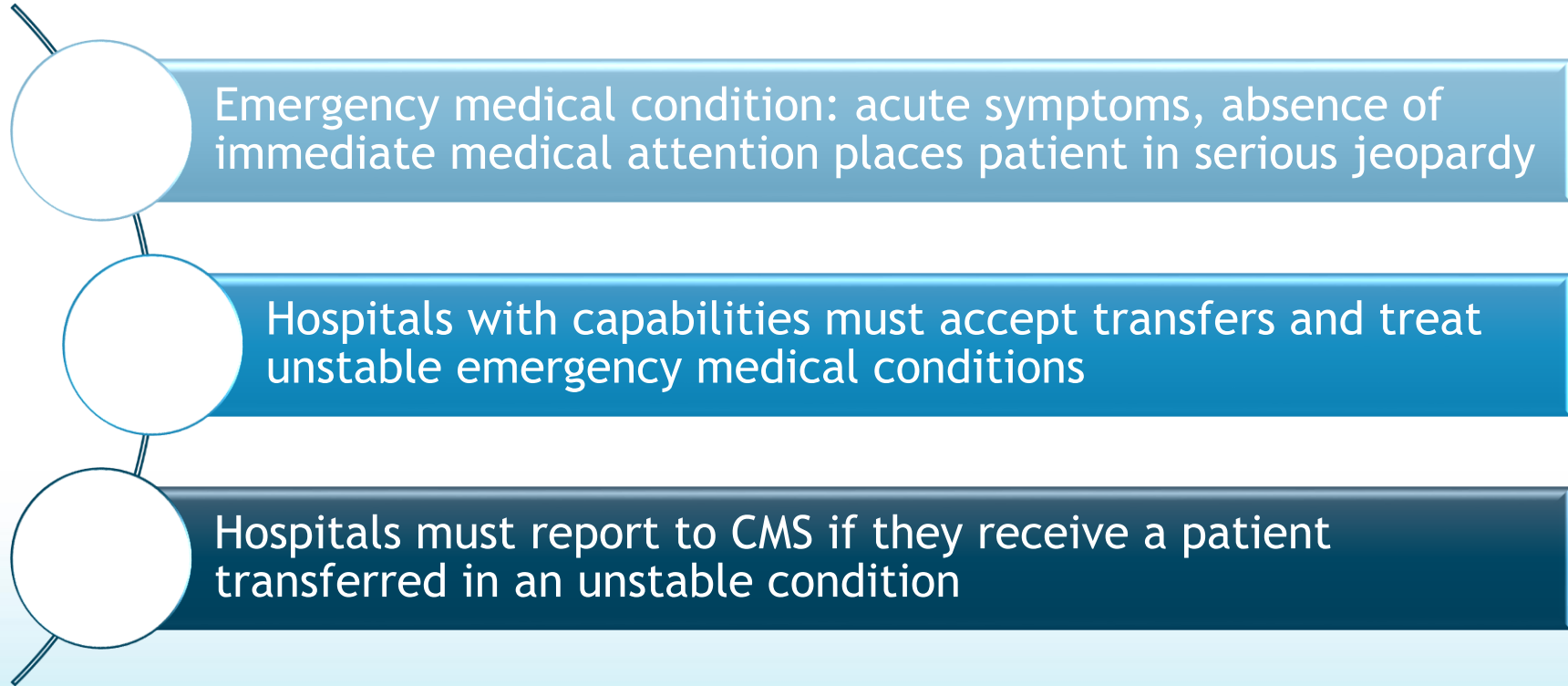
## ▶ EMTALA

- ▶ Requires hospitals to provide exam and stabilizing treatment
- ▶ Appropriate transfer if hospital unable to stabilize, or upon patient request
- ▶ Cannot consider insurance coverage or ability to pay
- ▶ Signage notifying patients of rights





## ▶ EMTALA



## ▶ EMTALA violation

### Hospital Settles Case Involving Patient Dumping Allegation (April 2018)

- ▶ Hospital in Iowa entered into a \$90,000 settlement agreement with the Office of Inspector General (OIG) to resolve allegations that it failed to provide an adequate medical screening exam and stabilizing treatment and inappropriately transferred a patient.
- ▶ 54-year-old man transported by ambulance to the emergency department (ED) complaining of shortness of breath, chest pain, and diaphoresis. ED physician screened patient and consulted on-call cardiologist. Patient's condition worsened and he was intubated.
- ▶ On advice of cardiologist, ED physician began transcutaneous pacing. He did not request nor did on-call cardiologist present to ED to examine the patient.
- ▶ ED physician requested transfer to nearby hospital for transvenous pacemaker.
- ▶ Patient was transferred to receiving hospital 3 hours after he first presented. A pacemaker was placed, but patient expired shortly after.

## ▶ EMTALA resources

- ▶ [GPO Publishing Office](#)
- ▶ [Examination and Treatment for Emergency Medical Conditions and Women in Labor](#) (U.S. Government Printing Office)
- ▶ [The Sullivan Group](#)
- ▶ [Emtala.com](#)
- ▶ [EMTALA resources](#) (Centers for Medicare & Medicaid Services)
- ▶ [EMTALA online](#) (Health Law Resource Center)
- ▶ [American College of Emergency Physicians](#)

# Corporate compliance

## ► Corporate compliance program

Compliance plan: Statement of healthcare organization's intention to conduct itself ethically in regard to business operations, government regulations, and patient care

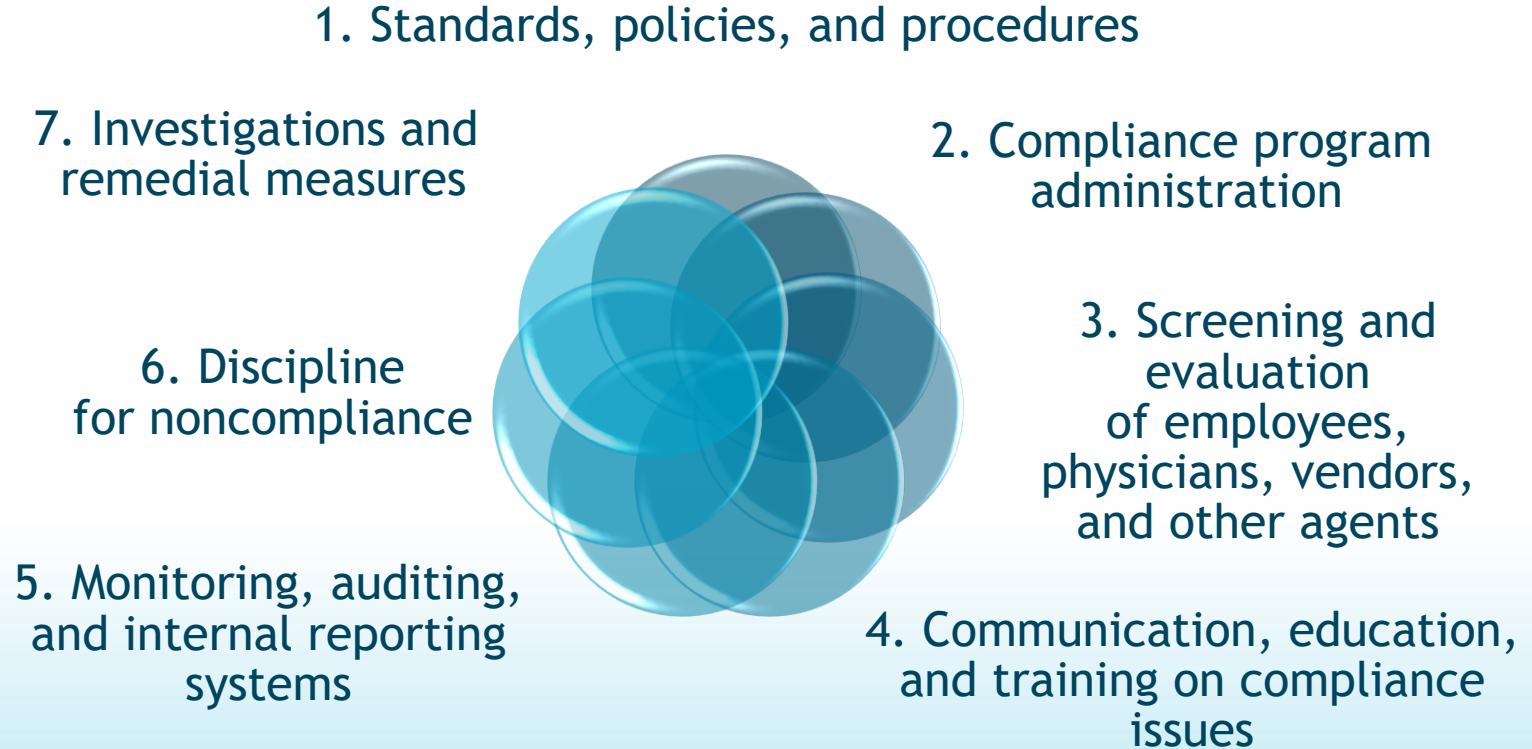
Detects and prevents violations of law by agents, employees, officers, and directors of the business

Federal law requires healthcare organizations and practices to develop and implement a compliance program

## ► Office of Inspector General (OIG)

- Protects the integrity of the Department of Health and Human Services (HHS) programs and health and welfare of beneficiaries
- Guiding documents encourage healthcare entities to develop compliance program and monitor adherence to applicable regulations
- Recovered more than \$2.77 billion, 428 criminal and 383 civil actions in first half of fiscal year 2016
- Corporate integrity agreements (CIAs) negotiated with entities in exchange for not being excluded from participating in federal healthcare programs

# ► Seven fundamental elements of a program



## ► Specifics of a compliance program

Integrates mission, values, and ethical principles with code of conduct

Has coding and overpayment policies and procedures in place

Has guidelines for internal and external compliance program audits

Develops an annual compliance work plan

Reports compliance program activity to the governance board/committee

Creates process to identify and disclose conflicts of interest

Monitors government sanction lists for excluded individuals/entities

Communicates compliance information throughout the organization

Applies appropriate disciplinary action when noncompliance is substantiated

Ensures that overpayments to payers are refunded in a timely manner



## ► Compliance violation

### Pediatrician Settles Case Involving False Claims (July 2018)

- New Jersey physician entered into a \$336,298.52 settlement agreement with the Office of Inspector General (OIG), resolving allegations that she knowingly presented to Medicaid claims for items or services that she knew or should have known were not provided as claimed and were fraudulent.
- OIG allegations: (1) Physician failed to personally perform or directly supervise services billed under her national provider identifier (NPI) number because she was either not present in the United States or in the state of New Jersey; (2) resubmitted previously denied claims; and (3) submitted claims under her NPI number for services performed by noncredentialed providers who were not supervised by the physician.

## ► Corporate compliance resources

- Compliance Guidance (U.S. Department of Health and Human Services, Office of Inspector General)
- Compliance Resources (U.S. Department of Health and Human Services, Office of Inspector General)
- Compliance Resource Material (U.S. Department of Health and Human Services, Office of Inspector General)
- Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (U.S. Department of Health and Human Services, Office of Inspector General)
- Practical Guidance for Health Care Governing Boards on Compliance Oversight (U.S. Department of Health and Human Services, Office of Inspector General)
- Corporate Integrity Agreements (U.S. Department of Health and Human Services, Office of Inspector General)

# The Joint Commission and other accrediting bodies

## ► The Joint Commission

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Accredits and certifies 21,000 healthcare organizations and programs in the United States

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Mission: Improve healthcare by evaluating healthcare organizations and inspire them to provide safe, effective, and high quality care

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Nation's oldest and largest standards-setting and accrediting body in healthcare

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Received Centers for Medicare & Medicaid Services (CMS) Deeming Authority in 2008; accredits nearly 500 hospitals of all sizes

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Integrates CMS Conditions of Participation with the ISO 9001 Quality Management Program

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Collaborative survey teams visit annually; each visit functions as a checkup on successes, not as an investigation of faults

## ► Healthcare Facilities Accreditation Program (HFAP)

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CMS Deeming Authority in 1965; survey team consists of physician, nurse, and hospital administrator

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Standards clear; accreditation requirements tied to the corresponding Medicare Conditions of Participation

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Standards includes those that enhance patient safety

## ► **National Committee for Quality Assurance (NCQA)**

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Private, not-for-profit organization founded in 1990, dedicated to improving healthcare quality

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Accredited health plans must meet 60+ standards and report on performance in 40+ areas to earn NCQA's seal of approval

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Standards promote adoption of strategies to improve care, enhance service, and reduce costs

## ► Benefits of accreditation

Strengthens  
patient safety  
efforts

Promotes  
community  
confidence

Improves risk  
mitigation and  
reduction  
strategies

Provides deeming  
authority for  
Medicare  
certification

Provides  
customized and  
intensive review  
of organization

May reduce  
liability  
insurance costs



# ▶ The Joint Commission and accreditation resources

- ▶ [The Joint Commission Resources](#)
- ▶ [About Joint Commission Resources](#)
- ▶ [The Joint Commission, Hospital Resources and Tools](#)
- ▶ [Healthcare Facilities Accreditation Program](#)
- ▶ [Accreditation by Healthcare Facilities Accreditation Program](#)
- ▶ [DNV - GL Hospital Accreditation](#)
- ▶ [National Committee for Quality Assurance](#)

## ► Quiz question

Under EMTALA, what is a hospital *not* required to do?

- A. Provide medical screening exam and stabilizing treatment
- B. Have signage indicating a patient's right to receive emergency treatment
- C. Ask the patient about insurance coverage at check-in
- D. Transfer the patient to another hospital if the hospital does not have the capability to provide appropriate care



## ▶ Response

Under EMTALA, what is a hospital *not* required to do?

C. Ask the patient about insurance coverage at check-in

Rationale: Under EMTALA, hospitals must provide a medical screening exam and stabilizing treatment when a patient presents to an emergency room for treatment without consideration of insurance coverage or ability to pay.

## ► Disclaimer

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