

WHAT EVERY ADMINISTRATOR NEEDS TO KNOW ABOUT THE ESSENTIAL ROLE OF THE COMPLIANCE AND ETHICS OFFICER IN LTPAC

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Learning Objectives

Upon completion of this program, the participant will:

- ❖ Identify key responsibilities for the Compliance and Ethics Officer
- ❖ Distinguish Federal requirements from state specific requirements
- ❖ Review requirements for facility-wide Emergency Preparedness Plan
- ❖ Explain components of a written emergency communication plan for internal and external emergencies and disasters
- ❖ List necessary documentation that must accompany each resident if evacuation is necessary
- ❖ Understand the importance of participating in training on facility emergency preparedness
- ❖ Establish role competency guidelines for the Compliance Officer referencing Element 2- Compliance Program Administration
- ❖ Evaluate and document Compliance Officer competency
- ❖ Annual evaluation, coaching, corrective action, professional development

History of Healthcare Compliance

- ❖ US False Claims Act (FCA) 31 U.S.C. §§ 3729 - 3733 was enacted in 1863 during the Civil War. Congress was concerned that suppliers of goods to the Union Army were defrauding them
- ❖ In the late 1990s, the Office of Inspector General (OIG) began a major initiative to support healthcare professions in establishing a compliance program for their offices, organizations, and practices.
- ❖ Then, the Affordable Care Act of 2010 made compliance programs mandatory for all skilled nursing facilities (SNFs) with oversight and enforcement by the Office of Inspector General.
- ❖ In March 2013, compliance programs became a SNF condition of participation.
- ❖ The Centers for Medicare & Medicaid Services (CMS) began oversight of compliance and ethics programs as part of the annual survey process effective November 28, 2019.



What is Fraud?

- ❖ Crimes of guile and deceit
- ❖ Reckless disregard for compliance with statutes, rules, and regulations
- ❖ Criminal Fraud versus Civil Fraud

What is Abuse?

- ❖ Abuse is defined as a corrupt practice or custom. Examples include:
 - Practices resulting, directly or indirectly, in unnecessary increased costs
 - Overuse of medical services, products, or both
 - Medically unnecessary services or products*

*"Abuse." *Merriam-Webster.com Dictionary*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/abuse>. Accessed 21 Feb. 2022.



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Why is Compliance Important?

An effective Compliance and Ethics program will protect clients in the following ways:

- Regulatory protection
- Prosecutorial protection
- Whistleblower protection
- Professional liability protections
- Financial protection

Who Polices Corporate Compliance?

- ❖ Several government agencies are charged with enforcement and oversight of corporate compliance.
 - Office of Inspector General (OIG)
 - Department of Justice (DOJ) and the US Attorney's Office
 - Federal Bureau of Investigation (FBI)
 - State Medicaid Fraud Control Units (MFCU)
 - The Office for Civil Rights (OCR)
 - Private payors
 - Qui Tam litigants



Compliance and Ethics Program – OIG Requirements



Element 2: Compliance Program Administration Overview

Governing Body: The facility must have a Governing Body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

Compliance and Ethics Officer: The Governing Body has appointed an individual to serve as its Compliance Officer with the following duties:

- Fraud, Waste, and Abuse Role
- Privacy Role
- Data Security Role
- Human Resources Role
- **Compliance and Ethics Committee:** The facility has appointed a Compliance and Ethics Committee to support the Compliance Officer in fulfilling his/her responsibilities
 - The Compliance Committee and the Privacy Committee can be one in the same

WHY Competency Is Important

For professionals, competency for those working in Compliance Management means demonstrating their proficiency and skill in the discipline

For organizations, competency should validate the Compliance Officer's compliance management knowledge, skill base, and critical competencies.

WHO SHOULD CONSIDER COMPLIANCE TRAINING?

- Quality and Risk Management Professionals
- Healthcare Executives
- Healthcare professionals with the requisite background
- Non-Clinical Healthcare Professionals with the requisite background

The Compliance and Ethics Officer

- ❖ The Compliance Officer is appointed by the Governing Body
- ❖ The Compliance Officer responsibilities include (but are not limited to):
 - The day-to-day oversight of the compliance and ethics program
 - Encouraging staff to report suspected fraud, waste, or abuse, and other improprieties without fear of retaliation
 - Monitoring compliance issues by regularly communicating with other departments within the facility
 - Maintaining a detailed log of all issues brought to their attention pertaining to compliance



The Compliance Officer reports to the Compliance and Ethics Committee, which meets no less than quarterly

The Compliance and Ethics Officer

- ❖ The Compliance and Ethics Officer is responsible for:
 - Developing and maintaining all compliance-related policies and procedures.
 - Making recommendations to the Company for changes to reflect updates in expectations enumerated in applicable laws, rules, and regulations.
 - Ensuring that all staff members have acknowledged the receipt of, and fully understand, the Code of Conduct.
 - Ensuring adherence to the Compliance Program: Every employee is bound by its conduct requirements.
 - Overseeing the day-to-day operation and oversight of the Compliance Program.
 - Ensuring that the appropriate authority approves or rejects in writing any and all amendments or modifications of Policies and Procedures, the Compliance Program and/or the Manual in accordance with this policy and procedure.

The Compliance and Ethics Officer

- ❖ Compliance Officer relationship to the Governing Body:
 - Overall responsibility for operation and oversight of the Compliance Program belongs to the Governing Body.
 - Ultimate authority to approve changes to the Compliance Program rests with the Governing Body which acts upon the receipt of recommendations from the Compliance Committee in relation to amendments or modification of policies and procedures or the Compliance Program.
 - The Governing Body may not delegate its authority to approve or reject material changes to policies and procedures, the Compliance Program, and/or the Manual.
 - The Governing Body may delegate its authority to approve an amendment or modification to the Compliance and Ethics Committee or the Compliance and Ethics Officer if the change is a technical change.

Element 2: Privacy Administration

- ❖ Distinguish the responsibilities of the Governing Body, the Privacy Officer, and the Privacy Committee in the development and implementation of the Company Privacy Program



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Privacy Officer: Program Oversight (2)

Ensures that future Company initiatives are structured to safeguard patient privacy

Remains current and advises on new technologies to protect data privacy

Evaluates privacy implications of any future on-line, web-based applications

Serves as liaison to government agencies, industry groups, and other interest groups in matters relating to Company privacy practices

Tracks any pending data privacy legislation and seeks to influence that legislation as appropriate

Conducts, at least annually, a review of the implementation of the minimum necessary provision

Conducts, at least annually, a review of access control logs

Data Security Administration

A data security risk assessment is conducted at least yearly

- ❖ Technology specific
- ❖ Examines the data network from the outside and inside to identify security vulnerabilities
- ❖ Performed:
 - Prior to the design of a secure network/security infrastructure
 - At any time to ensure that an organization is not vulnerable to the latest network, operation system, or application exploits



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Human Resources Administration

- ❖ The facility must verify the license or certificate of any employee required to hold such a license or certificate prior to hire and periodically as determined by the Administrator and/or Human Resources
 - Prior to hire, HR verifies that a license or certificate is current and bears the applicant's signature
 - Before an applicant begins work, a license or certificate must be verified with the appropriate agency:
 - RNs and LPNs – Board of Nursing
 - CNAs and NAs – Abuse Registry
 - May include therapists, dietitians, social workers, etc.



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Other Human Resource Concerns

Re-hiring of union staff

Re-hiring of non-union staff

Nepotism

Light Duty

Document Management

- ❖ The Compliance Officer audits the Company's document management program and updates the document management program to ensure that the policies meet requirements. Records:
 - Are retained for at least the minimum period as stated in applicable state or federal law or regulation, or according to record retention requirements dictated by the Company's insurance carriers
 - That may substantially affect the obligations of the Company are retained for a period of time that will reasonably ensure the availability of those records when needed
 - Are developed and maintained to document the Company's compliance with all relevant laws
 - Related to reports of violations are preserved in accordance with law and in a manner that will ensure maximum protection under the attorney-client privilege and attorney work product doctrine

Document Management (2)



- ❖ Company employees and agents create only documents which are:
 - Required by law
 - Necessary for job performance or compelled for business necessity
 - Needed to obtain or follow legal advice
 - Memos or letters created by employees must accurately reflect the events
 - Documents may only be distributed:
 - To the addressee(s) and those identified as requiring a copy
 - To those persons within and outside of the Company on a need-to-know basis
 - Other copying, distribution, or possession of documents is prohibited
 - Employees may not receive or possess documents that are not necessary to their regular job performance
 - An employee should not have a copy of a document unless he or she created the document, is the intended addressee/designated recipient, or the document was transmitted as an attachment to a document sent to the employee.
 - Unauthorized possession of Company documents is a violation of Company policy

Record Retention

❖ Destruction of records takes place per a standard policy to ensure that the Company does not deliberately destroy records in anticipation of a specific problem

- Premature destruction is a violation of Company policy
- A document clearly marked as a “cc” may be destroyed by the designated recipient of the copy if no longer needed

❖ Destruction Schedule

- Records are uniformly destroyed upon expiration as determined by the Compliance Officer
 - Prior to records destruction, the Compliance Officer notifies associates so that the destruction schedule can be interrupted for cause by someone in a position of authority
 - For cause includes service of legal process, notification from governmental agencies, request of the Compliance Committee or Legal Counsel

Guideline Overview

U.S. Sentencing Guidelines

False Claims Act

Medicaid fraud enforcement

HIPAA Privacy Rule

Healthcare Fraud Statute

Anti-Kickback Statute

The Medicare Program

Compliance and Ethics Program CMS Requirements

A facility must demonstrate compliance with these requirements:

- Written compliance and ethics standards, policies, and procedures
- High-level organizational personnel with overall responsibility for compliance
- Communicate/teach standards, policies, and procedures to staff, contractors, and volunteers
- Mandatory participation in the Compliance and Ethics Program
- Monitoring and auditing systems to detect criminal, civil, and administrative violations
- Reporting system for any affected individuals to report violations anonymously
- Consistent enforcement, including discipline for failure to detect and report a violation
- Not delegate authority to those with known history of criminal, civil, or administrative violations
- Non-retaliation non-retribution policy for reporting

CMS Additional Requirements – Organizations with Five or More Facilities

Organizations that operate five or more facilities must include in their compliance and ethics program:

- A designated compliance officer for whom the compliance and ethics program is a major responsibility, and who reports directly to the governing body and is not subordinate to the general counsel, chief financial officer, or chief operating officer
- Designated compliance liaisons located at each of the operating organization's facilities
- A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in F895 §483.95(f) Compliance and Ethics Program.

Difference Between Compliance and Ethics Program and QAPI Program

Compliance and Ethics Program

- ❖ *Purpose:* Focus on Fraud, Waste, and Abuse prevention and detection
- ❖ Compliance Officer responsible for day-to-day oversight
- ❖ Regular meetings of a Compliance and Ethics Committee
- ❖ Provides reports to the Governing Body
- ❖ Ensures closure on QAPI committee identified exposures

Quality Assurance Performance Improvement Program

- ❖ *Purpose:* Focus on developing, implementing, and maintaining an effective, comprehensive, data-driven program dedicated to systems and outcomes of care and quality of life
- ❖ QAPI champion leads in conjunction with top management
- ❖ Requires regular meetings of QAA/QAPI Committee
- ❖ Provides reports to the Governing Body
- ❖ Reports exposures/risks to the Compliance and Ethics Committee

How Compliance and Ethics Officers can help mend the quality crisis

Compliance
leaders for
quality of care

Corporate
Compliance for
board members

Compliance
reporting
process

Whistleblowers

Compliance
tracking log

Compliance
structure

Creating a
compliant
culture

Why Emergency Preparedness?

- ❖ Plan adequately for both natural and man-made disasters
- ❖ Prepare to meet the needs of residents during disasters and emergency situations
- ❖ Coordinate with external emergency preparedness systems
- ❖ Ensure the emergency preparedness program is aligned with State and local emergency plans and pandemic plans



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Emergency Preparedness Plan

- ❖ Identifies business functions essential to the facility's operations that should be continued during an emergency
- ❖ Identifies risks or emergencies that the facility may reasonably expect to confront
- ❖ Identifies contingencies for which the facility should plan
- ❖ Considers the facility's location
- ❖ Assesses the extent to which natural or man-made emergencies may cause the facility to cease or limit operations
- ❖ Determines arrangements that may be necessary with other healthcare facilities or other entities to ensure essential services could be provided during an emergency



A Preparedness Plan Fosters Teamwork

- ❖ Better anticipate and plan for needs
- ❖ Rapidly respond as a facility
- ❖ Integrate with local public health and emergency management agencies and healthcare coalitions' response activities
- ❖ Rapidly recover following the disaster



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All Hazards Continuity of Operations Plan

Develop a continuity of operations plan using an all-hazards approach to address:

- ❖ Bomb threats, earthquakes, evacuations, hot/cold extreme weather, tornadoes, internal/external fires, floods, hazardous material/waste spills, emerging infectious disease (EID) outbreaks and pandemics (Influenza, Ebola, Zika Virus, COVID-19, and others that may require modifications to facility protocols to protect the health and safety of patients, such as isolation, personal protective equipment (PPE), cohorting by infection type, consistent assignments, screening and testing, and other measures), missing residents, shelter preparedness, power outages, loss of water, loss of heat or cooling, snow storms, active shooter and other workplace violence, and any other hazard that could potentially impact the facility directly and indirectly. (Indirect could interrupt necessary utilities, supplies, or staffing.)
- ❖ Determine all essential functions and critical personnel.

Conduct a Risk Assessment

- ❖ A risk assessment is a process facilities use to assess and document potential hazards that are likely to impact their geographical region, community, facility, and patient population
- ❖ It uses an “all hazards” and integrated approach that identifies hazards, capacities and capabilities that can address a wide spectrum of emergencies:
 - Natural
 - Man-made
 - Facility, such as care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks
 - Interruptions in the normal supply of essentials, such as water and food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable)
 - Missing residents
- ❖ A risk assessment identifies gaps and challenges that should be addressed in developing the emergency preparedness program

Special Needs and At-Risk Populations

Identify individuals in your facility who may need additional response assistance, including those who:

- ❖ Have physical and mental disabilities
- ❖ Are from diverse cultures and racial and ethnic backgrounds
- ❖ Have limited English proficiency or are non-English speaking
- ❖ Have chronic medical disorders
- ❖ Have pharmacological dependency
- ❖ Are frail and totally dependent on staff
- ❖ Are dependent on machines (oxygen, feeding pumps, mechanical lifts, etc.)
- ❖ Require isolation precautions
- ❖ Others



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Planning for Safe Evacuation

- ❖ If the local community, region, or state declares a state of emergency and is requiring a mandatory evacuation of the area, facilities should abide by these laws and mandates.
- ❖ Establish a triaging system for evacuation that may consider the most critical patients first, followed by those less critical and not dependent on life-saving equipment. Identify who (specifically) will be tasked with making triage decisions.
- ❖ Considerations for prioritization may be based on acuity, mobility status (stretcher-bound/wheelchair/ambulatory), and location of the unit, availability of a known transfer destination.
- ❖ Plan for communication of patient care requirements to the in-taking facility, such as attaching a hard copy of a standard abbreviated patient health condition/history, injuries, allergies, treatment rendered, and family member/representative contact information.
- ❖ Alternate communication method such as satellite phones for contacting evacuation assistance.

Planning for Safe Evacuation (2)

- ❖ Description of how medications will be transported, including ensuring their protection under the control of a registered nurse.
- ❖ Procedures for protecting/transporting residents' medical records.
- ❖ Identify how residents/patients, their families, staff, and others will be notified of the evacuation, and communication methods that will be used during and after the evacuation.
- ❖ Identify staff responsibilities and how residents/patients will be cared for during evacuation, and a back-up plan if there aren't sufficient staff.
- ❖ Describe procedures to ensure residents/patients dependent on wheelchairs and/or other assistive devices and critical supplies/equipment are transported so their equipment is protected, and their personal needs met during transit (e.g., incontinent supplies for long periods, transfer boards, other assistive devices).
- ❖ Tracking method to account for all residents and staff during and after an emergency/evacuation.

When Evacuating:

Plan how to send all necessary patient information and have it readily available, including at least:

- Patient name
- Age
- DOB
- Allergies
- Current medications
- Medical diagnoses
- Current reason for admission
- Blood type
- Advance directives
- Next of kin/emergency contacts



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Reentry Following Evacuation

The facility must have a reentry plan that describes:

- ❖ Who will authorize reentry to the facility after an evacuation
- ❖ The procedures for inspecting the facility, including collaboration with the Department of Health
- ❖ How it will be determined it is safe to return after an evacuation.
- ❖ The appropriate considerations for return travel
- ❖ Notification to residents, families, and representatives

Emergency Preparedness Training



- ❖ Initial emergency training takes place during orientation to ensure needed training is not delayed
 - Is provided to all new and existing staff, individuals providing services under arrangement, and volunteers, *consistent with their expected role*
 - Includes individuals who provide services on a per diem basis, such as agency nursing staff and any other individuals who provide services on an intermittent basis and would be expected to assist during an emergency
- ❖ Focuses on policies and procedures
- ❖ Annual emergency preparedness training
- ❖ All emergency preparedness training must be documented

Emergency Preparedness Drills and Testing

- ❖ The facility must evaluate the effectiveness of training as well as the overall emergency preparedness program
- ❖ Testing includes conducting drills and/or exercises to:
 - Test the emergency plan
 - *Including unannounced staff drills*
 - Identify gaps and areas for improvement
- ❖ Participate in a community-based, full-scale exercise, or individual, facility-based mock disaster drill annually. It should be a collaborative exercise which involves, at a minimum, local or state emergency officials to develop community-based responses to potential threats .
- ❖ Training and testing must be documented
 - Facilities should ensure their emergency preparedness programs are aligned with their State and local emergency plans/pandemic plans.



Putting Compliance into Action

Know and Follow	Know and follow federal, state, and local laws, policies and procedures, regulations, and guidelines that apply to one's job
Act	Act with integrity
Ask	Ask questions when uncertain about a situation
Strive	Strive to do the right thing in everything one does

Last Words for Compliance Success

Normalize compliance as a way to assess and address risk in all departments

Encourage the difficult questions: See something... say something

Focus on Quality

Document Training and Education

Maintain a culture of accountability

Document - If it isn't documented, it didn't happen



Questions?



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