

# FHCA 2019 Annual Conference & Trade Show

## CE Session #17 – Compliance 101

Monday, August 5 – 12:30 to 1:30 p.m.

Windermere X – Legal/Regulatory/Survey

### Upon completion of this presentation, the learner will be able to:

- Understand the required elements of an effective Compliance Program
- Review the regulatory/statutory requirements
- Understand how to implement a Compliance Program in long term care

### Seminar Description:

As part of the Requirements of Participation (RoP) published in October 2016, nursing centers must have a Compliance and Ethics Program that meets certain requirements. Starting on November 28, 2019, CMS and state survey agencies will be authorized to issue survey deficiencies under federal Ftag F895 to centers that do not have an effective Compliance Program. This session will prepare attendees to be in compliance.

### Presenter Bio(s):

**Karen Goldsmith** currently serves as FHCA's Regulatory Counsel and previously served as Florida Health Care Association's Legal Counsel since 1980. She is on the American Health Care Association's Legal Subcommittee and served as its Chair for three years. She is active in the American Health Lawyers Association and served as Chair of their Long Term Care subgroup for two years. She has been published in several books produced by AHLA. She practices primarily in long term care.

**Hazel Mahoney** has been a Registered Nurse since 1978, training originally in England, working in the Middle East and then moving to Florida in 1990. She has worked in hospitals, long term care centers and physician provider organizations in various capacities. Hazel completed her BA in Health Administration through the University of Dundee distance learning program in 2012. Hazel has developed, implemented and monitored clinical risk management programs for three long term care companies in Florida, moving into Compliance in 2013. In 2014, Hazel achieved certification in Health Care Compliance and Health Care Privacy Compliance. She has developed, implemented, and now oversees comprehensive Ethics and Compliance Programs for different operating companies which meet OIG guidelines.

**Rebecca Schachter** has worked for Clear Choice Health Care in several different capacities since 2008. She currently holds the position of Director of Corporate Compliance which incorporates the overall implementation and evaluation of systems within Clear Choice Health Care. Her background as both a Registered Nurse and Nursing Home Administrator have given her the knowledge-base to oversee the diverse areas that encompass compliance in the skilled nursing profession.



# Compliance 101

FHCA RISK COMPLIANCE COUNCIL- COMPLIANCE WORK GROUP

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# Hazel Mahoney

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# Compliance Work Group Members

- ▶ Hazel Mahoney, Airmed Health Services, Chair
- ▶ Karen Goldsmith, Goldsmith and Grout, PA
- ▶ Rebecca Schachter, Clear Choice Health Care
- ▶ Robin Bleier, RB Health Partners, Inc.
- ▶ Rachel Carlock, Consulate Health Care
- ▶ Pam Harris, Health Services Advisory Group
- ▶ Tommy Hulse, Gulf Coast Health Care
- ▶ Julie Ann Kemman, Health Care Professional Consulting Services, Inc.
- ▶ Joseph Tempelberg, Plaza Health Network
- ▶ Tim Wombles, Broad and Cassel, LLP

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## Objectives

- ▶ Understanding of required elements of an effective Compliance Program (Hazel)
- ▶ Regulatory/Statutory requirements (Karen)
- ▶ Better understanding of how to implement a Compliance Program in LTC (Rebecca)

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## REQUIRED ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

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## POLICIES AND PROCEDURES

- ▶ Required
  - ▶ Code of Conduct
  - ▶ Reporting concerns
  - ▶ Document Retention
  - ▶ Fraud, Waste and Abuse
    - ▶ Deficit Reduction Act
- ▶ Discipline/department specific

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## OVERSIGHT

- ▶ Board?
- ▶ Ethics and Compliance Officer/Committee

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## EFFECTIVE EDUCATION

- ▶ Compliance Program, Code of Conduct, Reporting, HIPAA, policy on non-retaliation
- ▶ More than 5 buildings:
  - ▶ Orientation
  - ▶ Annual
  - ▶ As needed
- ▶ Strongly recommend for all facilities

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## AUDITING AND MONITORING PROGRAM

- ▶ Audit – systematic review of specific area in order to detect fraud
- ▶ Monitor – ongoing surveillance of a system
- ▶ High risk, high frequency, problem prone areas
- ▶ Year round
- ▶ Facility specific
  - ▶ Discipline specific?

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## COMMUNICATION

- ▶ Process for reporting concerns
- ▶ Education on how to report, what to report

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## RESPONSE/PREVENTION

- ▶ Prompt response
- ▶ Objective, thorough investigation
  - ▶ Documentation
  - ▶ Log
- ▶ Education
- ▶ Strict policy of non-retaliation for good faith concerns

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## ENFORCING STANDARDS

- ▶ Well publicized disciplinary guidelines; available to staff
- ▶ Consistent across all levels of the organization

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PROGRAM EVALUATION

- ▶ Annual review of program effectiveness



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Karen Goldsmith



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REGULATORY AND STATUTORY REQUIREMENTS



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## Interpretive Guidelines:

- ▶ Much of what the surveyors will be looking for in assessing your compliance plan will be set out in the interpretive guidelines:
  - ▶ Not out yet
  - ▶ Expected to be comprehensive
  - ▶ Will be critically important because this is a new area to surveyors and they will be dependent on the IG's
  - ▶ IG's do not have effect of law but are procedural so are given deference

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## 42 CFR 483.85 Compliance and ethics program (F895)

- ▶ Implemented beginning on November 28, 2019
- ▶ DO NOT WAIT AND EXPECT TO HAVE ONE IN PLACE AT THE LAST MINUTE
- ▶ Surveyors will be looking for content and effectiveness not just a chapter in a manual
- ▶ Likely will question staff on how the plan works and how it is being implemented

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## Definitions:

- ▶ Compliance and ethics program:
  - ▶ Relates to a facility
  - ▶ "Program of the operating organization"
  - ▶ Reasonably designed, implemented and enforced to be effective
  - ▶ Prevents and detects criminal, civil and administrative violations
  - ▶ Promotes quality of care
  - ▶ Includes elements set out in regulation

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## Definitions, continued

- ▶ High level personnel is defined as "individual(s) who have substantial control over operating organization" or in making policy
- ▶ In other words, those at the top must buy into and participate in various ways in the compliance program
- ▶ The operating organization is the individual or entity that operates the facility – could be licensee but could it also be management company?

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## Required Components (42 CFR 483.85(c):

- ▶ Written standards
- ▶ Written policies
- ▶ Written Procedures
- ▶ Must reduce the prospect of violation of law
- ▶ Must promote quality of care
- ▶ Must have individual to whom violations can be reported
- ▶ Needs alternate method of reporting
- ▶ Anonymity for reporter

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- ▶ No retribution
- ▶ Disciplinary standards with consequences for all staff
- ▶ Must include contractors
- ▶ Also volunteers
- ▶ Must have high level personnel to oversee compliance such as CEO, board members, directors

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- ▶ Must have sufficient authority and resources to assure compliance
- ▶ Control over discretionary authority
- ▶ Communication of standards, policies and procedures
- ▶ Mandatory training

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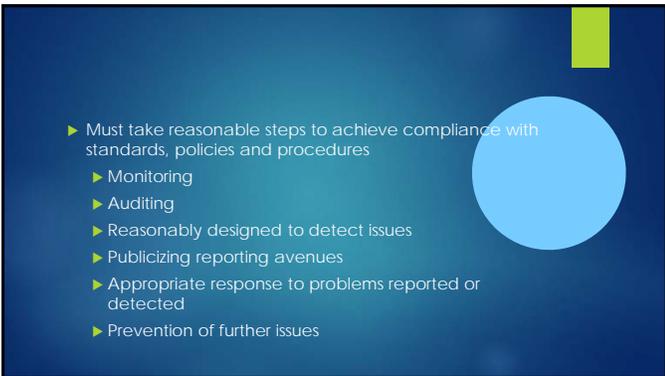
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- ▶ Must take reasonable steps to achieve compliance with standards, policies and procedures
  - ▶ Monitoring
  - ▶ Auditing
  - ▶ Reasonably designed to detect issues
  - ▶ Publicizing reporting avenues
  - ▶ Appropriate response to problems reported or detected
  - ▶ Prevention of further issues

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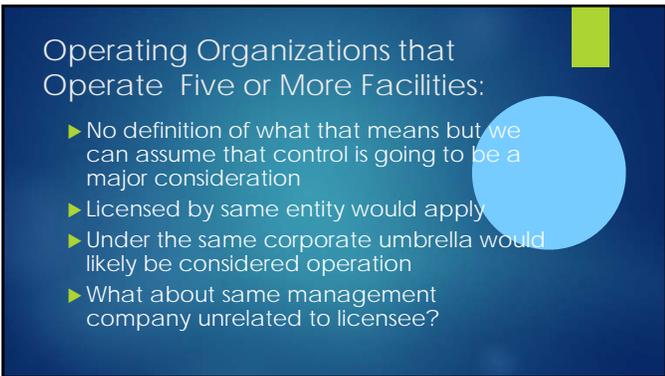
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Operating Organizations that Operate Five or More Facilities:

- ▶ No definition of what that means but we can assume that control is going to be a major consideration
- ▶ Licensed by same entity would apply
- ▶ Under the same corporate umbrella would likely be considered operation
- ▶ What about same management company unrelated to licensee?

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▶ In addition to the other requirements must:

- ▶ Give annual training on the program
- ▶ Must be mandatory
- ▶ A designated compliance officer for whom the operating organization's compliance and ethics programs is a major responsibility
- ▶ Must report directly to governing body and not subordinate to general counsel, CEO or COO
- ▶ Must have designated "compliance liaisons" at each facility

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### Annual Review

▶ The operating organization for each facility must review its program annually and revise as needed to "reflect changes in laws and regulations and within the organization and its facilities"

▶ Purpose of review is to ensure that your program:

- ▶ Promotes quality of care
- ▶ Recognizes changes and responds to them
- ▶ Improves the performance of the program and the facility in deterring, reducing and detecting issues

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PROPOSED REGULATIONS FROM CMS



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- Compliance and Ethics:
  - Program must be reasonably designed, implemented and enforced to be effective in preventing and detecting criminal, civil and administrative violations
  - Must promote quality of care
  - Required components for all facilities
    - Effective written standards, policies and procedures
    - Reasonably capable of reducing violations
    - Specific individuals within the organization with overall responsibility for program
    - Must be in high level positions
    - Sufficient resources and authority



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- Due care to avoid giving substantial discretionary authority to individuals in organization who have propensity to engage in violations
- Effective communication with staff, contract service personnel and volunteers
- Includes mandatory training in accordance with role
- Monitoring and auditing systems
- Effective reporting system
- Consistent enforcement
- Discipline including for failure to report
- Steps to ensure a problem detected has an appropriate response



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- Organizations with 5 or more facilities:
  - *Have a more formal program that includes established written policies defining standards and procedures to be followed by its employees*
  - *Develop a program...appropriate for the complexity of the organization....*

All facilities must have periodic review and revision

Remember these are proposed rules which are not yet effective



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Rebecca Schachter



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▶ Implementing a Compliance Program



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Start Early Implementation

▶ Implement prior to deadline:

- ▶ Element 1 - Written Policies/Code of Conduct
- ▶ Element 2 - Training/Education
- ▶ Element 3 - Compliance Officer designation & Oversight
- ▶ Element 4 - Reporting Hotline
- ▶ Element 5 - Monitoring, Auditing and Internal Reporting
- ▶ Element 6 - Non-retaliation and Non-intimidation
- ▶ Element 7 - Investigations and Remediation
- ▶ Element 8 - Disciplinary Policies are established



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"Implementing an effective compliance program may require a significant commitment of time and resources by all parts of the organization." Federal Register/Vol. 65, No. 52

- #1. Develop written compliance standards, procedures, and practices that guide the nursing facility and the conduct of its employees throughout day-to-day operations.
- #2. Implement staff knowledge using **Competency-Based Education, One-on-one education & through group in-services**
- #3. Review & Educate during Orientation, Annually & As Needed.
- #4. Annual Review of program by Leadership Team required.

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## Competency-Based Education

- ▶ An approach to teaching and learning that helps the learner understand in "stages".
- ▶ Learner works on one competency at a time – which is likely a small component of a larger learning goal.

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## Competency-Based Education

- ▶ A. Learners advance to next stage of Compliance curriculum once they demonstrate understanding.
- ▶ B. Competencies include explicit, measurable, transferable learning objectives with clear documentation .
- ▶ C. Learners receive timely support based on their individual needs related to Compliance content.
- ▶ Results of education is documented & accessible to regulators.

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## One-on-One Education

- ▶ Start Now!
- ▶ Electronic education programs available
- ▶ Person-to-person /Face-to-face on-site training with each individual
- ▶ Can be inefficient if subject matter is needing to be spread to 100% of staff and vendors.

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## Group In-Services

- ▶ Start Now!
- ▶ Utilize All-Staff meeting approach
- ▶ Ensure comprehension by utilizing post-in-service quizzes
- ▶ Document attendance

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## Whom do you Educate?

- ▶ Education is provided to the following:
  - ▶ Employees of the center
  - ▶ Physicians that interact with the center
  - ▶ Suppliers/Vendors of the center
  - ▶ Nursing Facility agents and/or Contractors

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## Ongoing Compliance

- ▶ Participation in compliance education should be a condition of employment; and/or
- ▶ initial/continuing contract relationship (i.e. physicians, vendors, etc.)

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## Annual Evaluation of the Program

- ▶ Ongoing monitoring & auditing process of Compliance Program is required
- ▶ Compliance Director & Center Compliance Representative in constant communication throughout the life of the Compliance Program
- ▶ Annual review & sign off of Compliance Program documented both by the operating organization and at the Center Level

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## Questions?

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Thank you!



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For Follow Up Questions, please contact Kim Broom, FHCA Liaison to the Risk/Compliance Council and your questions will be presented to the Risk/Compliance Council for response.



[kbroom@fhca.org](mailto:kbroom@fhca.org)  
863-899-0693

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