

Requirements of Participation Phase 3 Beyond the Basics: Keys to an Effective Compliance Program

Sarah Couture
Glena Jarboe
November 1, 2019



1

Disclosures

- John Dailey: Nothing to disclose
- Sarah Couture: Nothing to disclose



Speakers



John D. Dailey
 President
 Management Advisors, Inc.
 Lexington, KY
 jodalley@fochtgroup.com
 +1.859.509.8343 Direct

HEALTH CARE COMPLIANCE; LONG TERM CARE ADMINISTRATION AND OPERATIONS; HUMAN RESOURCES

- Licensed nursing home administrator
- Certifications: CHC, SPHR, SHRM-SCP
- More than 20 years of experience in long-term care operations, administration, and human resources.
- Particular expertise assisting organizations with developing and implementing compliance programs and labor/employment compliance.



Sarah Couture
 Senior Director
 Ankura
 Chicago, IL
 sarah.couture@ankura.com
 +1.859.421.7357 Direct

HEALTHCARE COMPLIANCE; RESEARCH BILLING COMPLIANCE; CLINICAL AND MEDICAL NECESSITY AUDITING

- Registered Nurse
- Certifications: CHC, CHRC
- Compliance program expertise in academic medical center, hospital, physician practice, pharmacy, long-term care, and research settings, including program development and assessment, risk assessment, interim staffing, and training.
- Over 18 years of clinical experience in hospital, physician practice, pediatric, skilled nursing facility, Federally Qualified Health Center, and free clinic settings.

3

Session Objectives

1. Describe the basic framework of a compliance program as outlined in the Requirements of Participation
2. Customize a compliance risk assessment and develop an effective work plan
3. Enhance the effectiveness of the compliance program by growing beyond the basics

4

The Basic Framework of a Compliance Program as Outlined in the Requirements of Participation

5

Just When We Thought We Knew...

July 2019 CMS Announcement:

-CMS announced revisions to the SNF Requirements of Participation Phase 3 Compliance & Ethics program

-October 4, 2016 Federal Register gave great detail about compliance and ethics programs in SNFs

-July 18, 2019 Proposed Rule made some changes to the RoP just as November was quickly approaching

6

Reform of Requirements for Skilled Nursing Facilities

FEDERAL REGISTER:

October 4, 2016 Final Rule in Federal Register Vol. 81, No. 192 (81 Fed Reg 68688)

<https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities>

Published July 18, 2019 Proposed Rule in Federal Register Vol. 84, No. 138 (84 Fed Reg 34737)

<https://www.federalregister.gov/documents/2019/07/18/2019-14946/medicare-and-medicaid-programs-requirements-for-long-term-care-facilities-regulatory-provisions-to>

OIG Compliance Guidance 2000:

<https://oig.hhs.gov/authorities/docs/cpgnf.pdf>

OIG Supplemental Compliance Guidance 2008: https://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf

7

What is Going On?

- What exactly changed?
- What stayed the same?
- How does this impact your Compliance & Ethics Programs efforts?

You came to the right session!

8

Reset Your Clocks

- The 2019 Proposed Rule reset the timetable for the Compliance and Ethics RoP component.
- Implementation is delayed until one year following the effective date of the Proposed Rule



9

New Proposed Rule Requirements

- Written compliance standards, policies, and procedures
- High-level program oversight
- Sufficient resources and authority to ensure compliance
- A screening process for positions with discretionary authority
- Effective communication of compliance standards to staff, contractors, and volunteers
- Reasonable steps to achieve compliance, such as auditing & monitoring
- Consistently enforced disciplinary actions

10

New Proposed Rule Requirements

- Appropriate response to violations, and prevention of similar future violations
- An alternate method of reporting suspected violations anonymously
- Periodic review and revision of the compliance program
- In addition, organizations with five or more facilities must also:
 - Have a more formal program with established written policies defining standards and procedures
 - Develop a program appropriate for complexity of the operating organization and its facilities

11

Written Compliance and Ethics Standards, Policies and Procedures

- Establish written standards, policies and procedures
- Reasonably capable of reducing criminal, civil, and administrative violations
- The 2019 Proposed Rule removed examples such as program contact and disciplinary standards
- The OIG Voluntary Guidance from 2000 may help more as it gives examples such as the Code of Conduct and specific risk areas where facilities should have written policies:
 - Quality of care, Resident Rights, Billing and Cost Reporting, Employee Screening, Kickbacks, Inducements, & Self-Referrals, Creation & Retention of Records

12

High-Level Program Oversight

- Must assign specific individuals within the “high-level personnel” of the operating organization with overall responsibility to oversee compliance with the operating organization’s compliance and ethics program’s standards, policies, and procedures.
- No change to the definition of high-level personnel: “Individuals who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization”.
- BUT, the Proposed Rule removed examples of who that may be: CEO, member of the Board of Directors, or directors of major divisions.
- Bottom Line: Someone with authority high up in the organization must be responsible for the organization’s compliance program.

13

Sufficient Resources and Authority to Ensure Compliance

The designated “high-level personnel” must have resources and authority to reasonably assure compliance with the standards, policies, and procedures.

Resources

Is there a sufficient budget and staffing to carry out the Compliance Program?

Authority

Top of organization must be in support of and grant appropriate authority so that the program has “teeth” to be able to enforce standards and Program requirements

14

Screening Process

- There are no changes between the 2019 Proposed Rule and the 2016 Final Rule stating that facilities are required to take due care not to delegate substantial discretionary authority to individuals with a propensity to wrongdoing.
- The OIG guidance documents also discusses conducting thorough background and criminal record checks, OIG Exclusions, and checking applicable licensure and certifications.



15

Effective Communication of Compliance Standards to Staff, Contractors, and Volunteers

- A facility must take steps to effectively communicate the standards, policies, and procedures of the compliance and ethics program to staff, contractors, and volunteers (consistent with the volunteer's role).
- Requirements include but are not limited to mandatory training, orientation programs, and disseminating information in a practical manner.
- Good Idea: Develop compliance orientation and training materials that explain what the Program requires, and require participation.

16

Reasonable Steps to Achieve Compliance: Auditing/Monitoring

- Steps to achieve compliance include but are not limited to utilizing auditing and monitoring systems reasonably designed to detect criminal, civil, and administrative violations
- Should apply to staff, contractors, and volunteers
- Implement a reporting system that allows individuals to report suspected violations without fear of retribution.
- Start simple, and add more complexity over time and as the Program develops
- Determine who will audit, how audits will be conducted, a consistent format for each audit report, and to whom audit results will be reported

17

Consistently Enforced Disciplinary Actions

- Consistent enforcement through appropriate disciplinary mechanisms including disciplinary action for failure to detect or report violations
- Ensure compliance and behavior expectations are clear
- Collaborate with Human Resources



18

Appropriate Response to Violations and Prevention of Similar Future Violations

- Take all reasonable steps to respond appropriately to a violation and to prevent further similar violations
- This includes making necessary modifications to the Compliance Program in response to violations
- Consistent process for responding to violations and poor audit results
- Incorporate Root Cause Analysis into the process
- Document actions taken in response to violations, and actions taken to prevent future similar violations

19

Alternate Method of Reporting

- The Proposed Rule adds section (c) (9):
 - “The facility has an alternate method of reporting suspected violations anonymously”
- In the 2016 Final Rule, an anonymous reporting system was mentioned under the section dealing with facilities taking reasonable steps to achieve compliance with auditing and monitoring. Has its own section under the 2019 Proposed Rule.
- Consider contracting with a third-party vendor
- Bottom Line: Employees must have a way to report suspected violations - one of the ways must be anonymously.
- Good Idea: Publicize how to report, the Hotline number, names, phone numbers, and email addresses of Compliance Program contacts. Educate employees!

20

Periodic Review and Revision of the Compliance Program

- The 2019 Proposed Rule removes the “annual review” requirement from 2016.
- 2019 wording: “The operating organization for each facility must periodically review and revise its compliance program to identify necessary changes within the organization and its facilities.”
- Compliance versus Operations?
- What’s best practice?
- Program review can be performed with collaboration with the compliance staff, compliance committee, and senior leadership to review the year’s compliance successes and opportunities for improvement
- Where does QAPI and the Facility Assessment fit in?

21

Additional Requirements For Organizations with Five or More Facilities

Big changes from the 2016 Final Rule to the 2019 Proposed Rule

In the 2016 Rule, organizations that operate 5 or more facilities must provide annual mandatory compliance program training, designate a compliance officer who reports to the governing body and is not subordinate to the general counsel, CFO, or COO, AND designate compliance liaisons at each facility.

2019 Proposed Rule

Operating organizations that operate 5 or more facilities and facilities with corporate level management of multi-unit nursing home chains must:

- #1. Have a more formal program that includes established written policies defining the standards and procedures to be followed by its employees.
- #2. Develop a compliance and ethics program that is appropriate for the complexity of the operating organization and its facilities.

22

Customize a Compliance Risk Assessment and Develop an Effective Work Plan

23

WHY Perform Risk Assessment: The Foundation of Compliance Program Development

An EFFECTIVE compliance program must be based on an accurate risk profile

- Otherwise, your compliance program may be activity for the sake of activity. Could be a “paper program.”
- A compliance program that is aligned with and actively seeking to mitigate compliance risk will bring far more benefit to your organization than a program designed to merely satisfy a surveyor’s checklist.

Not specifically required by the Final Rule, BUT...

- Risk Assessment guides application of the Seven Elements:
 - What policies do you need? Where should you audit?
What content should be in your education?
- Risk Assessment helps bring together the operation departments where the risks “live,” allowing collaborative discussion, mitigation, and ownership of corrective action plans by operations.

24

OVERVIEW: Annual Risk Assessment and Work Plan Development

- **Collaborate** with operations management/compliance committee and compliance staff, if applicable, and senior leadership to **assess risk**, program successes, and areas for opportunity
- **Rank risks** to help determine **priorities** for the upcoming year
- Develop a 12-month **work plan** based on risk assessment and program review to **guide compliance program activity**



25

WHAT is Risk Assessment: An Effective Compliance Program is Based on an Accurate Risk Profile

- What are you doing (the activity or work that represents the risk)?
- What are the rules and regulations that govern what you are doing?
- How do you mitigate the risk?



26

WHAT is Risk Assessment: Developing your Risk Profile-Identify External Risks

- LTC Requirements of Participation
- OIG Compliance Program Guidance
- OIG Work Plan
- Industry and regulatory changes
- Enforcement actions
- Advisory Opinions
- Special Advisory Bulletins



27

WHAT is Risk Assessment: Developing your Risk Profile- Identify Internal Risks

- Culture
- Tone at the top
- Organizational structure
- Number of facilities
- Integration of facilities
- Mergers/acquisitions
- Staff interviews
- Current and past survey results
- Internal monitoring and auditing results
- Collaboration with business leadership
- Electronic or paper records
- Outsourced services
- Resident fund processes
- Coding and billing practices

28

WHAT is Risk Assessment: Identify and Understand what Rules and Regulations Apply

- LTC Requirements of Participation
- False Claims Act
- Anti-Kickback Statute
- Stark Law
- Deficit Reduction Act
- HIPAA
- OSHA
- Social Security Act
- Civil Monetary Penalties Law



29

WHAT is Risk Assessment: Common Risks in LTC Based on What Activities are in your Business Model

- PDPM, generally
- Skilled Nursing Facility
 - Quality of care
 - Sufficient staffing
 - Resident care plans
 - Medical necessity
 - Medication management/psychotropic/controlled substances
 - Resident safety
 - Staff screening
 - Claims submission, case mix
 - Anti-Kickback statute
 - Physician self-referral

30

WHAT is Risk Assessment: Common Risks in LTC Based on What Activities are in your Business Model

- OT, PT, SLP
 - Medical necessity
 - Documentation
 - PDPM implications
- DME
- Home Health
 - Eligibility/medical necessity and recertification
 - High improper payment rates
- Pharmacy
 - Controlled Substances
 - Billing for drugs not dispensed
 - Part D requirements
 - Certain modifiers
 - Specialty Drugs

31

WHAT is Risk Assessment: Common Risks in LTC Based on What Activities are in your Business Model

- Personal Care Services
 - Fraud
 - Abuse and neglect
 - Unallowable room and board
- Inpatient Rehabilitation
 - Medical Necessity
 - Documentation Requirements

32

WHO performs Risk Assessment: Collaboration of Compliance and Operations

- Collaborate!
 - Can't be done in isolation
 - Involve those whose operational areas "own" the risks (include contracted services, i.e., therapy)
 - Compliance committee or other group
- Consider a 2-layer collaboration approach
 - An "in the weeds"/management group who know well and understand the details of the risk areas and internal controls; the "working group" of compliance risk assessment
 - A higher-level/C-Suite group to validate results of working group's assessments from a wider angle

33

WHO performs Risk Assessment: Collaboration of Compliance and Operations

- Consider a team(s) of
 - Chief Operating Officer
 - Chief Financial Officer
 - Chief Medical Officer
 - Coding
 - Billing
 - Legal counsel
 - Privacy
 - Vendor management/supply chain
 - Marketing/Liaisons
 - Human Resources
 - Nursing
 - Physicians
 - Pharmacy
 - Therapy
 - Information Technology
 - Risk
 - Quality and Safety
 - Other?

34

HOW-TO Perform Risk Assessment: Steps

1. Develop and roll out Risk Assessment process
 - Documented process and plan
 - Ensure key players'/collaborators' understanding
 - Regular, often annual, and ongoing as risks change
2. Develop preliminary list of risks
 - Based on what Compliance Officer knows
 - Ensure encompasses all operational risk areas and considers External and Internal Risks (slides 27-28)
3. Solicit input from all high-risk areas
 - Did you identify all potential risk areas and players?
 - Update/complete list with input from key players

35

HOW-TO Perform Risk Assessment: Steps

4. Meet with risk assessment group to rank the risks
 - Consider/rank Impact, Probability, and adequacy of Internal Controls of each potential risk area
 - Rank the Impact, Probability, and Internal Controls by
 - High, Medium, Low, OR
 - 1-5, OR
 - 1-10
5. Analyze rankings in order of risk
 - Add numbers/rankings for both Impact and Probability
 - Subtract number/ranking for adequacy of Internal Controls
 - List risks in numeric/rank order
6. Ensure senior leadership input and awareness of results of risk assessment
 - Allow an opportunity for senior leadership/high-level review of risks assessment to ensure risk were not under-identified

Review Referenced guidance (slide 42) for additional tips and best practices for compliance risk assessment.

36

Accurate Risk Assessment Informs Compliance Program Priorities: Compliance Work Plan

- With leadership input, determine how many highest ranked risks can be addressed by the Compliance Program
 - You can't address every risk! Too many! Not enough time!
 - DOJ Evaluation of Corporate Compliance Programs discusses how effective programs prioritize risk and put efforts toward high risk areas
- Make a "Plan" to address the highest risk areas: The Compliance Work Plan

37

Accurate Risk Assessment Informs Compliance Program Priorities: Compliance Work Plan

- What needs to be done to address the risk?
 - Partner with those who understand the risk the most (in operations)
 - Research and understand regulatory expectations regarding the risk
 - Apply/utilize the Seven Elements to evaluate the risk
 - What policies exist? Are they sufficient?
 - What education and training has been provided? Is it sufficient?
 - Have there been compliance reports or investigations regarding this risk?
 - Perform an audit of the risk area to identify issues, determine extent of issue(s), etc.
- Document in Work Plan

38

Accurate Risk Assessment Informs Compliance Program Priorities: Compliance Work Plan

Risk	Risk Ranking	Responsible Party	Mitigation Actions/7 elements	Expected Completion Date	Follow up Corrective Action Plan	Progress: Follow up/ Auditing Plan
Controlled Substances						
Medical Necessity, Documentation, and Billing						
Anti-Kickback						
Stark Law						
Exclusions						
Licensing and Credentialing						

39

Accurate Risk Assessment Informs Compliance Program Priorities: Compliance Work Plan TIPS

- Regularly communicate risk assessment and Work Plan to senior leaders and Board of Directors
- Discuss updates and status at regular Compliance Committee or other meetings with operations leaders and managers
- While Compliance will review policies, education, audit, etc., relative to the risk, and Corrective Action Plan regarding the operational risk should be the responsibility of the applicable OPERATIONS department
- Ensure completion of Corrective Action Plans. Provide guidance if needed and a due date
- Compliance should ensure adequate follow up, and re-audit as necessary to ensure effectiveness of Corrective Action Plans

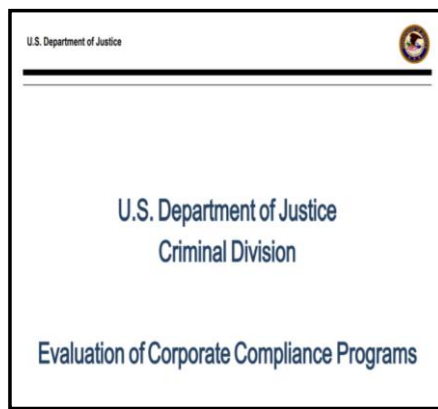
40

Growing Beyond the Basics: Enhancing the Effectiveness of the Compliance Program

41

Beyond the Basics: Enhancing Compliance Program Effectiveness

- Perform a self-check up using OIG and DOJ Effectiveness Guidance documents, or get an outside perspective



- From Department of Justice (DOJ)
- Factors that prosecutors should consider (in investigations, decisions about bringing charges, negotiating pleas/agreements) to determine "the adequacy and effectiveness of the corporation's compliance program..."

<https://www.justice.gov/criminal-fraud/page/file/937501/download>

42

Beyond the Basics: Enhancing Compliance Program Effectiveness



- From OIG (Office of Inspector General-Health and Human Services)
- 52 pages of suggestions
- Some used frequently, some not at all
- Frequency and use will be based on size and risk areas
- Not intended to be a check list or to do all

<https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf>

43

Beyond the Basics: Enhancing Compliance Program Effectiveness

- Involve operations via a Compliance Committee
 - Collaboration and accountability
- Engage the Board
 - Provide education on compliance oversight responsibility
 - <https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>
- Conduct a compliance culture and knowledge survey
 - Partner with HR or quality on annual employee survey
 - Who is the Compliance Officer? Do you know how to report a compliance violation? Do employees fear retaliation for making good faith reports?

44

Beyond the Basics: Enhancing Compliance Program Effectiveness

- Invest in compliance incentives
 - Prizes or trinkets for areas that complete compliance training on time
 - Performance evaluation tied to compliance metrics
 - Promotions based on compliance
 - Bonuses contingent on compliance training, compliant operations
- Celebrate a Compliance and Ethics week
 - 1-week marketing blitz
 - Posters, emails, video from leadership highlighting Compliance Program
 - Take snacks and Compliance Program info to department meetings

45

Questions?

Thank You!

46

AHCA[®]
AMERICAN HEALTH CARE ASSOCIATION

NCAL[®]
NATIONAL CENTER FOR ASSISTED LIVING

IMPROVING LIVES *by*
DELIVERING SOLUTIONS *for*
QUALITY CARE