

Compliance and Ethics Programs

Under the Revised Requirements of Participation
Ken Burgess



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Timing of Requirements

- As of November 28, 2019, SNFs are required to have “effective compliance and ethics programs”
- In 2000 and 2008, the Office of Inspector General of U.S. Dept. of Health and Human Services issued voluntary guidance to SNFs on “corporate compliance programs”
- The new ROP requirement essentially makes those mandatory
- Substance of the underlying requirements not changed
- What was “voluntary” is now “mandatory”
 - With a few tweaks/clarifications

What is a Compliance and Ethics Program

- Required by 42 CFR section 483.85
- Corresponding Ftag is F895
- Definition:
 - A set of policies, procedures and structures designed to promote compliance with all applicable state and federal laws
 - Both SNF-specific laws
 - And general healthcare-specific laws (ex: Elder Justice Act)
 - And, relatedly, to “minimize” the potential for violation of these laws
- May refer to it as “the do the right thing” law/requirement

What is a Compliance and Ethics Program

- The “ethics” part of the name
 - Not really talking here about clinical ethics
 - Compare to facility with “Ethics Committee” to make difficult clinical or end of life decisions
 - Where issue is not “is this legal,” but what’s the best thing to do
- Here, “ethics” means imbedding a culture of ethical compliance in all aspects of facility/company operations
- Hence, the “do the right thing law”

What is a Compliance and Ethics Program

- At Ftag 895, CMS has outlined a set of 8 elements it expects to see in a “compliance” Compliance & Ethics Program
- And 3 additional elements for entities that “operate” 5 or more SNFs
 - In this number, you only count SNFs
 - Not a home health, or hospice your company also owns/operates
 - Whether you meet this “5 or more standard” is not based solely on how multiple SNFs are owned or the corporate structure
 - Focus is on “operates”
 - So, our advice, if you own, operate or manage 5 or more SNFs, assume these 3 additional requirements apply to you

A 10,000 Foot View/Definition of Compliance and Ethics Programs

- A set of structures for teaching about compliance
 - Training folks on your expectations (laws, policies, procedures)
 - Monitoring performance to ensure compliance
 - Reporting mechanisms for potential violations
 - Disciplining violations
 - Correcting violations and preventing recurrence
 - Periodically reviewing the above structures and modifying as needed
- And sets of underlying, substantive expectations expressed in law, policies and procedures

A 10,000 Foot View/Definition of Compliance and Ethics Programs

- Think of compliance/ethics program as a house
- You have a roof, walls, floors and furniture
 - These are the “things” that make up the house
- You also have people living in the house under a set of rules and expectations
- The structural elements of your compliance program are the roof, walls, floors and furniture
- The rules and expectations that govern life within those walls, roofs, floors are the underlying “ethics and compliance” part of your program

A 10,000 Foot View/Definition of Compliance and Ethics Programs

- So, a compliance and ethics program is:
 - A set of policies, laws, standard of practice that all persons at all levels of the organization are expected to and required to meet
 - And a set of “procedures” that drive how those policies and laws will:
 - Be communicated to everyone
 - Be trained on periodically
 - Be reported when violated
 - Be reviewed periodically for effectiveness and any need for modifications
 - Be enforced through consistent discipline at all levels of company
 - Be reported to ownership/senior management (annual/as needed)
 - Result in remedial measures designed to prevent recurrence

The Elements of a Compliance/Ethics Program

- The eight core elements for all SNFs
- The three additional elements for entities that “operate” 5 or more SNFs
- After we review these, I’ll point you to a potential starting point/document you can use and modify to meet each element

Element 1

- Develop compliance and ethics standards that are “likely to be effective” in reducing criminal, civil and administrative violations and promote quality of care
 - Need a code of conduct/mission statement committing entity to compliance
 - Designating contact for reporting of violations
 - Creating methods for staff, contractors, volunteers to report suspected violations, including anonymous reporting method
 - Creating, advertising, and following consistent disciplinary standards at all levels of operations/ownership for violations
 - Need a non-retaliation statement

Element 1 (continued)

- This includes the above structural elements
 - Mission statement, how to report, consequences of violating standards or failing to participate in compliance program, who to report to, etc.
- And the underlying substantive requirements you expect staff/owners/volunteers, contractors to meet:
 - Quality of care requirements (the regs)
 - Billing requirements
 - Repayment requirements (60-day repayment rule)
 - Elder Justice Act reporting for elder abuse/crimes
 - HIPAA
 - And others

Element 2

- Assigning high level person(s) to oversee the compliance and ethics program
 - Someone with authority over operations and with authority to make changes
 - And enforce compliance
 - If you have 4 or fewer facilities, this can be an existing staff position
 - No magic title required, like “Compliance Officer”
 - Key is what authority do they have
 - Can be administrator
 - For 5 or more SNFs, we’ll cover later—it’s different
 - Regardless of size, this position cannot be subordinate to the General Counsel, CFO or COO—must be independent

Element 3

- Commit sufficient resources to the compliance and ethics program to reasonable assure compliance with laws, policies and expectations
- CMS: we expect facilities to use their Facility Assessment to determine what resources are needed for this component
 - We expect the Facility Assessment to be linked closely to the compliance program
- Example: you have a unique behavioral health unit and nobody with expertise, or no policies unique to BH AND you have a negative outcome in that population

Element 4

- Using due diligence and documenting your efforts to ensure the person put in charge of compliance and ethics program does not have the “propensity” to engage in criminal, improper civil or regulatory behavior
 - Focuses on who you choose to “run” your program
 - How you vet them
 - How you monitor them
 - Criminal background checks
 - OIG’s list of excluded individuals/entities
 - Other public reporting sites (Medicaid, etc.)

Element 5

- Effective communication of compliance programs standards, polices and procedures to:
 - Staff, contractors and volunteers (as appropriate to their roles)
 - Required training
 - Publicizing your program and how to report
 - Posters in facility
 - Copies of compliance program to contractors/volunteers
 - Annual attestations by employees/contractors of compliance
 - Random interviews with staff/contractors re core elements of program
 - Consider training/attestations annually
 - See sample attestation clauses/forms

Element 6

- Taking reasonable steps to achieve compliance with your program's standards, policies and procedures
 - Includes routine auditing and monitoring systems
 - Of quality of care, billing, financial accounting/reporting
 - Your reporting mechanisms for those who suspect a potential violation
 - Including anonymous method(s) of reporting
 - And a non-retaliation policy
- Many/most of you already do this via various ongoing self audits
 - No need to recreate unless you don't have such systems

Element 7

- Consistent enforcement for violations of expectations (laws, policies, etc.)
 - Includes consistent discipline at ALL levels
 - Up to and including termination
 - And discipline for failing to detect & report suspected violations of law, policies and/or the compliance program expectations
- Check your employee handbook to ensure this is a component of job descriptions
 - And of job performance evaluations

Element 8

- Ensuring reasonable steps are taken to respond to violations and to prevent future violations
 - Including updates/modifications to policies, procedures AND the compliance program
 - Means having a response and remediation plan
 - May include:
 - Internal/external corrective action plan
 - Reporting, where required, to government agencies
 - Reporting/returning overpayments
 - Elder Justice Act reporting (suspected crimes against elders)

Entities Operating 5 or More SNFs: Element 9

- Conducting ANNUAL, mandatory compliance training
- The annual training not required for entities operating 4 or fewer facilities, but we recommend it
- This should be handled by the Compliance Officer but can use outside resources
- Should include training on your compliance program
- And policies/procedures unique to your entity

Entities Operating 5 or More SNFs: Element 10

- Designating a Compliance Officer whose “major” responsibility is the compliance/ethics program
- Cannot be subordinate to company lawyer, or CFO, COO
- Not someone located at one of your 5 or more facilities
- A “corporate person” with authority who reports to the owners, Board of Directors
- Can have other roles but the compliance program must be their “major” role

Entities Operating 5 or More SNFs: Element 11

- Designation a compliance liaison at each of the organization's facilities
 - A different role from Compliance Officer who is at corporate level
 - Can have other roles as well
 - Each company defines qualifications and role of this person
 - Main goal is to assist corporate Compliance Officer

The Question I Came to Have Answered

- What will CMS and DHSR expect from my facility on surveys after November 28, 2019
- Well
- CMS has issued NO Interpretive Guidance to surveyors yet on this Ftag
- So, nobody knows
- Including the survey agencies nationwide
- AT THIS POINT, we expect minimal focus on this requirement UNLESS you have a systemic survey issue which prompts surveyors to inquire about both your Facility Assessment and Compliance/Ethics Program

Anticipated Expectations at Post November Surveys

- You/your staff are able to answer these questions:
 - Do you have a Compliance and Ethics Program?
 - Have you had training on it and when?
 - What sorts of things were covered in the training?
 - Do you feel comfortable reporting suspected violations of law and facility policy?
 - Is there a way for you to report suspected violations without fear of retaliation?
 - To whom would you report violations and how can you report?
 - Is there an anonymous way for you to report issues?
 - Who is your facility Compliance Officer or Compliance Liaison?

Anticipated Expectations at Post November Surveys

- Possible questions for Administrator
 - Who is your Compliance Officer or Liaison?
 - How often do you conduct compliance/ethics training?
 - Who gets trained (staff, owners, contractors, volunteers as appropriate to their roles)
 - What are your reporting mechanisms for suspected violations?
 - Is there an anonymous reporting option/what is it?
 - Is there a policy against retaliation for reporters?
 - How does your facility/company respond to reports of suspected violations?
 - How involved in company ownership?
 - Do they get training/reports?
 - What resources have been dedicated to compliance/ethics?

Anticipated Expectations at Post November Surveys

- Show me your compliance program/documentation
 - Be sure to tell them whatever you hand them is the “house” or structure of your program
 - But your clinical/employment policies/procedures are also part of it
- How do you use your Facility Assessment in your compliance and ethics program?

HELP ME: What Resources Are Out There?

- AHCA/NCAL has:
 - Robust tool kit with
 - Program description
 - Question/answer document
 - Training videos on each of the 8 required compliance program elements
- You can use these to help develop your program
- And for training staff/owners/contractors/volunteers
- Includes a Risk Assessment Tool/checklist
- And a Compliance/Ethics Training Checklist

HELP ME: What Resources Are Out There?

- In 2012, we wrote for AHCA a Compliance Program “book”
 - The word “ethics” wasn’t part of the original nomenclature
 - But it’s the same thing
 - It contains all the same elements as Ftag 895
 - And some sample policies/procedures for the BIG areas
- That Guidance is actually referenced in the current AHCA/NCAL Toolkit, so it’s still being offered as a tool
- We have it in pdf and Word format



HELP ME: What Resources Are Out There?

- One option for you:
 - Take that document as a **STARTING POINT**
 - Modify it to fit your company/facility
 - Perhaps update it based on your Facility Assessment
 - Potentially add to it any policies/procedures you need
- If you do this, please remember to train on it and ensure that the procedures spelled out in it are actually being used in your company/facility
- It needs to be customized, reviewed annually and modified IF you choose this approach

A Word of Caution

- Temptation: let me “buy” a Compliance/Ethics book or use the Burgess/AHCA one
- Compliance & Ethics Program is not a book
- It’s a living/breathing program
- Minimally, you do need a “book/policy/document” that sets out the core structural elements of your program (compliance officer, committee, mission statement, code of conduct/expectations, commitment to training, enforcement, discipline, etc.)
- But, your existing billing, care and personnel policies are already part of your compliance program and can be incorporated into it by reference

Questions?

