

COUNTDOWN TO PHASE 3 SKILLED NURSING COMPLIANCE PROGRAMS - COMPONENT #8 - RESPOND AND TAKE CORRECTIVE ACTION

This is another article in a series discussing the complete overhaul of Part 483 to Title 42 of the Code of Federal Regulations the Requirements for States and Long-Term Care Facilities ("Final Regulations") by the Centers for Medicare & Medicaid Services ("CMS"). To view other articles in this series, click [here](#).

Beginning on November 28, 2019, surveyors will use the requirements detailed in 42 C.F.R. Section 483.85 in the Final Regulations to determine whether a skilled nursing facility's ("Facility") compliance and ethics program fulfills the requirements in the Final Regulations. One of the required components is that the Facility must respond and take corrective action when a violation is detected.

BACKGROUND AND PURPOSE OF A COMPLIANCE AND ETHICS PROGRAM

The Final Regulations created a new Section 483.85 requiring Facilities to have a compliance and ethics program. This regulation arises from Section 6102 of the Affordable Care Act, which added Subsection 1128I(b) to the Social Security Act (the "Act").

Section 483.85(c) sets forth the required compliance and ethics program components for all Facilities. Under those regulations, a compliance and ethics program means, with respect to a Facility, a program that has been reasonably designed, implemented and enforced so that it is likely to be effective in preventing and detecting criminal, civil and administrative violations under the Affordable Care Act and in promoting quality of care; and includes, at a minimum, the required components specified in the Final Regulations.

REQUIRED COMPONENT #8 - RESPOND AND TAKE CORRECTIVE ACTION

Section 483.85(c)(8) of the Final Regulations requires that once a violation has been detected, the Facility should take reasonable steps as identified in its program to respond appropriately to the violation and take corrective action. Depending on the seriousness of the violation, the Facility may need to make modifications to its program.

STATE OPERATIONS GUIDANCE TO SURVEYORS

CMS has not issued guidance on how surveyors will interpret and cite the compliance and ethics program requirement.

Absent guidance from CMS, surveyors will likely ask to see the compliance and ethics program documents. This could include requesting a copy of the Facility's process on how it will respond and take corrective action when a violation is detected.

OIG GUIDANCE - RESOURCES

In its 2000 memo titled "Publication of the OIG Compliance Guidance for Nursing Facilities," OIG wrote that "[d]etected but uncorrected deficiencies can seriously endanger the reputation and legal status of the nursing facility."

Once a violation has been detected, OIG expects the compliance officer or other management staff to "immediately investigate" to determine if a violation has occurred. If a violation did occur, the Facility must take "decisive steps" to correct the problem.

If the violation involves potential fraud, OIG would expect the Facility to conduct an internal investigation. This internal investigation would include document review and witness interviews. The Facility could hire outside consultants, including legal counsel, to assist with the internal investigation depending on the seriousness of the detected violation. OIG also suggests the Facility keep a written file of the internal investigation and corrective action. This would be key evidence in the event of a survey or demand for overpayment.

If employees of the Facility are a subject of the internal investigation, the employee may need to be suspended pending the outcome of the investigation. The Facility should also have a disciplinary policy in place that is consistently enforced when an employee is the subject of the internal investigation.

IMPLEMENTATION TIME FRAME

Beginning on November 28, 2019, surveyors will use the requirements detailed in Section 483.85 to determine whether a Facility's compliance and ethics program fulfills the requirements in the Final Regulations.

ACTION ITEMS

Facilities should:

- Implement a policy and procedure on how to respond and take corrective action when violations are detected;
- Assess what will be required to investigate and respond to the alleged violation;
- Keep a detailed file of any investigation; and
- Have a disciplinary process in place for employees who commit violations and ensure it is consistently enforced.

COMPLIANCE AND ETHICS PROGRAM TOOLKIT AVAILABLE

Hall Render has developed a compliance and ethics program toolkit to assist skilled nursing facilities in achieving compliance with Section 483.85 and the Final Regulations. For more information about the toolkit, please contact Sean Fahey at (317) 977-1472 or sfahey@hallrender.com.

If you have questions about this topic or would like assistance with the Phase 3 compliance and ethics program requirements, please contact:

- **Sean Fahey** at (317) 977-1472 or sfahey@hallrender.com;
- **Todd Selby** at (317) 977-1440 or tselby@hallrender.com;
- **Brian Jent** at (317) 977-1402 or bjent@hallrender.com; or
- Your regular Hall Render attorney.