

COUNTDOWN TO PHASE 3 - SKILLED NURSING FACILITIES NEED TO CREATE A COMPLIANCE AND ETHICS PROGRAM

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 Section 483.85 of the Final Regulations to determine whether a skilled nursing facility's compliance and ethics program fulfills the requirements in the Final Regulations.

BACKGROUND

On September 28, 2016, CMS released a complete overhaul of Part 483 to Title 42 of the Code of Federal Regulations, the Requirements for States and Long-Term Care Facilities. CMS's Final Regulations cover many regulatory requirements for long-term care facilities and create new compliance obligations for providers. The Final Regulations seek to target rehospitalizations, facility-acquired infections, overall quality and resident safety. The date for the implementation of the third and final phase of the implementation to of the Final Regulations is November 29, 2019.

Hall Render published an [overview](#) of Final Regulations components as well as Parts 1, 2, 3 and 4 in the series, which are located [here](#).

EXECUTIVE SUMMARY

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 a new Subsection 1128I(b) to the Social Security Act. The compliance and ethics program must have written compliance and ethics standards, policies and procedures that are designed to reduce the prospect of criminal, civil and administrative violations, as well as promote quality of care. Starting on November 28, 2019, surveyors will use requirements detailed in Section 483.85 to determine whether a facility's compliance and ethics program satisfies the requirements in the Final Regulations.

REQUIRED COMPLIANCE AND ETHICS PROGRAM COMPONENTS FOR ALL FACILITIES

New Section 483.85(c) sets forth the required compliance and ethics program components for all facilities.

These required components include:

- Written compliance and ethics standards, policies and procedures. This includes delegation of an appropriate contact to which individuals may report violations or suspected violations anonymously without fear of retribution.
- Assignment of individuals within the high-level personnel to oversee the compliance and ethics program of the facility. This includes the CEO, board members or directors of major divisions within the operating organization.
- High-level personnel are given sufficient resources and authority to ensure compliance with the written standards, policies and procedures.
- Due care must be exercised to not give discretionary authority to individuals the operating organization knew or had reason to know engage in criminal, civil and administrative violations under the Social Security Act.
- The compliance and ethics program must be communicated to staff and volunteers in accordance with their roles and contracted individuals.
- Implementation of monitoring and auditing systems that are reasonably designed to detect criminal, civil and administrative violations under the Social Security Act.
- Consistent enforcement of facility standards, policies and procedures through appropriate disciplinary mechanisms for failure to detect

and report compliance violations.

- Once a violation is identified, the operating organization must take all reasonable steps to appropriately respond to the violation and to prevent similar violations that would include modifications to existing compliance standards, policies and procedures.

ADDITIONAL COMPLIANCE COMPONENTS FOR OPERATING ORGANIZATIONS WITH FIVE OR MORE FACILITIES

Section 483.85(d) addresses additional compliance components for operating organizations with five or more facilities. In addition to the requirements set forth in Sections 483.85(a),(b),(c) and (e), operating organizations with five or more facilities must include these additional components in their compliance and ethics programs:

- Mandatory annual training program on the operating organization's compliance and ethics program.
- A designated compliance officer who reports directly to the operating organization's governing body. The compliance officer is not subordinate to the general counsel, chief financial officer or chief operating officer of the operating organization.
- Compliance liaison located at each facility of the operating organization.

REQUIRED ANNUAL REVIEW

Section 483.85(e) addresses the annual review of the operating organization's compliance and ethics program. The compliance and ethics program must be reviewed annually and revised for any changes in laws or regulations or changes within the operating organization.

INTERACTION WITH QAPI PROGRAM AND FACILITY ASSESSMENT

In CMS's responses to public comments on the regulations, CMS wrote that facilities should be integrating the information and data they collect or that arises out of their compliance and ethics programs into their Quality Assurance and Performance Improvement ("QAPI") program. The requirements for compliance and ethics and the QAPI programs should work together or be coordinated to not only ensure compliance with the requirements in the Final Regulations but also improvements in the quality of care provided to the residents.

CMS also wrote that it expects that all operating organizations would also use the facility assessment they developed in developing and maintaining their compliance and ethics programs. Operating organizations should use the facility assessment to determine the resources they need to devote to their compliance and ethics programs to reasonably ensure compliance with the requirements of the Final Regulations.

IMPLEMENTATION TIME FRAME

Beginning on November 28, 2019, surveyors will use requirements detailed in Section 483.85 to determine whether a facility's compliance and ethics program fulfills the requirements in the Final Regulations. CMS has not yet issued significant interpretive guidance on Section 483.85. It is likely that CMS will release additional interpretive guidance in an updated State Operations Manual or create a Critical Element Pathway before November 28, 2019.

ACTION ITEMS

- Facilities that do not already have a compliance and ethics program should begin putting one in place so that they are ready for survey enforcement.
- Facilities that have implemented compliance and ethics programs should review the new requirements against their existing programs and revise as necessary.

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 **Todd Selby** at (317) 977-1440 or tselby@hallrender.com.

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

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