



ARE YOU READY FOR PPACA'S MANDATORY COMPLIANCE AND ETHICS PROGRAM REQUIREMENT FOR NURSING FACILITIES AND SKILLED NURSING FACILITIES?

The Patient Protection and Affordable Care Act ("PPACA") requires a nursing facility or skilled nursing facility to have in place an effective compliance and ethics program by *March 10, 2013*. Specifically, Section 6102 states that

[o]n or after the date that is 36 months after the date of the enactment of this section [March 10, 2010], a facility shall, with respect to the entity that operates the facility (in this subparagraph referred to as the 'operating organization' or 'organization'), have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care consistent with regulations developed under paragraph (2).

The definition of the compliance and ethics program is important to analyze carefully. The statute defines a "compliance and ethics program," with respect to the above referenced facilities, as a program of the operating organization that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care, and includes *at least* the required components of the program, as defined below.

PPACA provides that the following eight components must be included in the program:

1. the organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this Act;
2. specific individuals within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures and have sufficient resources and authority to assure such compliance;
3. the organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this Act;
4. the organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required;
5. the organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this Act by its employees and other agents and by having in place and publicizing a reporting system, whereby employees and other agents could report violations by others within the organization without fear of retribution;
6. the standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense;



7. after an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including any necessary modification to its program to prevent and detect criminal, civil, and administrative violations under this Act; and
8. the organization must periodically undertake reassessment of its compliance program to identify changes necessary to reflect changes within the organization and its facilities.

The OIG Work Plan for FY 2012 expressly states that the OIG will "review the Medicare and Medicaid certified nursing home's implementation of compliance plans as part of their day-to-day operations and whether the plans contain elements identified in OIG's compliance program guidance." They will also "assess whether CMS has incorporated compliance requirements into Requirements for Participation and oversee provider implementation plans."

Unfortunately, there have not been any regulations published to date addressing this statutory provision. PPACA provides that by March 2012, the Secretary of Health and Human Services working with the Inspector General of the Department of Health and Human Services must promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program. However, as noted above, the final regulations covering these programs, as required by PPACA, have not been published.

Even though there are no final regulations relating to this specific provision, the OIG has previously provided guidance to nursing facilities. Prior to PPACA, the OIG issued compliance guidance to nursing facilities in the original "OIG Compliance Program Guidance for Nursing Facilities" published in March 2000, as well as supplemental guidance in 2008 titled, "OIG Supplemental Compliance Program Guidance for Nursing Facilities." This guidance (that may need to be updated in certain areas), as well as other OIG reports and guidance and other government guidance can serve as tools for facilities to utilize with respect to compliance programs. It is critical to note that each compliance and ethics program must be tailored to the issues of each facility.

In addition to the OIG guidance, recent cases concerning nursing facilities may provide insight. For example, there is a recent case involving Georgia nursing homes related to quality of care allegations. The United States Attorney's Office, as well as the State of Georgia, reached a settlement concerning False Claims Act allegations with respect to "inadequate and worthless wound care services to residents," among other allegations. This matter was initiated by the medical director for one of the nursing homes, who served as the relator in the case. A Corporate Integrity Agreement was also reached with the OIG containing a number of provisions concerning compliance and quality of care.

In conclusion, it is prudent for nursing and skilled nursing facilities to carefully review the above provisions. This article is only meant to provide a brief summary about the PPACA Section and should not be construed as legal advice. As noted above, a facility's compliance and ethics program must be tailored to the issues of the facility. Please contact Myla Reizen at 305.679.5716 if you have any questions about this article or would like assistance with your compliance program. We have significant experience in developing, evaluating, and implementing compliance and ethics programs, including parts, as well as the entire program.

— [Myla R. Reizen](#)



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