



CREATING A PPACA MANDATORY COMPLIANCE PROGRAM **by Kimberli Poppe-Smart**

Skilled nursing facilities (SNFs), organizations already heavy-laden with oversight and regulatory requirements, are the first health care providers targeted by HHS / OIG to incorporate a mandatory compliance program. The Patient Protection and Affordable Care Act of 2010 (PPACA) catapulted a once-voluntary health care compliance program into a regulated requirement.

Section 6102 of PPACA made changes to title XI of the Social Security Act (42 U.S.C. 1301 et seq.) that include a requirement that, effective March 23, 2013, skilled nursing facility and nursing facility operating organizations shall have an effective compliance and ethics program that prevents and detects criminal, civil and administrative violations under the Act and promotes quality of care consistent with regulations developed by the Secretary and Inspector General of the Department of Health and Human Services.

Section 6401 of PPACA established the requirement of a mandatory compliance program for all health care providers and suppliers, making it a condition of enrollment in Medicare. This section has no implementation deadline but does require HHS / OIG to establish core elements of the desired effective compliance program. To date, no implementing regulations have been issued that definitively guide providers in the establishment of the type of compliance and ethics program envisioned by the PPACA drafters and certainly no "model compliance program" referenced in the final rule has been made available as a guide. Nonetheless, following the eight minimum required elements noted in Section 6102, nursing facilities have adequate notice and impetus to put their programs in place.

The following eight elements are referenced in the final rule as the minimum components necessary to develop the type of compliance program envisioned:

1. Effective compliance standards and procedures followed by employees and agents;
2. "High-level personnel" with authority to assure compliance are assigned overall responsibility and are sufficiently resourced;
3. Substantial discretionary authority is not delegated to individuals whom the organization knew, or should have known, had a "propensity to engage in criminal, civil, and administrative violations";
4. Effectively communicate standards and procedures to all employees and agents;
5. Monitoring and auditing systems and a system to report violations without fear of retribution;
6. Consistent enforcement of standards through appropriate disciplinary actions;

7. Reasonably respond to the identified offense and steps to prevent further similar offenses;
and
8. Periodic reassessment of the organization's compliance program, making necessary changes to reflect organizational changes.

These eight elements incorporate the seven elements described in Chapter 8 of the 2010 U.S. Federal Sentencing Guidelines Manual (FSG), that have been relied upon as core elements of voluntary compliance program guidance. HHS / OIG looks to these specific elements because they incorporate prevention, detection, correction of inappropriate behavior and ensure compliance with all applicable federal laws, regulations and requirements.

There are risks inherent in not having a Compliance Program including the potential for exclusion from Medicare and Medicaid funding when enforceable, mandatory programs are not in existence. The greater risk, however, comes from the prevailing culture that may take hold in the absence of written policies, standards and practices that result in the submission of erroneous and fraudulent claims. In addition to program exclusion, such practices, if they remain unchecked, may bring civil penalties and criminal prosecutions.

The following are steps that you can take now towards meeting the intent of the Section 6102, in the absence of more directive regulations. Organizations are at varying levels of readiness with their Compliance Program. The following is a list of activities that will aid a new program in developing their foundation and will provide a check point for existing, more robust programs.

Conduct a risk/gap assessment of your current compliance efforts and develop an action plan to demonstrate your organization's commitment to achieving compliance with the mandatory requirements. Policies, procedures and standards that relay the organization's commitment to compliance are foundational. Policies may be added over time based upon trends in the industry and occasionally, a policy may become obsolete and be retired. Currently, there is a strong federal commitment, with financial backing, to find and confront fraud in long term care based on the failure to provide quality care. A more robust policy or series of policies directed at quality of care in the organization is timely in light of these federal efforts.

Within the assessment of your existing compliance plan and subsequent action plan, the following should be included:

- Review existing policies and procedures for currency, accuracy, applicability and completeness. Policies and standards should express the organization's commitment to compliance with all applicable laws. A sampling of policies to analyze include: Code of Conduct, Claims Submission, Reporting of Compliance Concerns and Investigation, Responding to External Compliance Investigations/Inquiries (including how to respond to search warrants, subpoenas or requests), HIPAA Privacy and Security Plan, Coding and Documentation, Disciplinary Guidelines, Compliance Officer and Compliance Committee.
- Establish a Compliance Plan, program and process. Identify the "high-level personnel" who is in charge of the compliance program and draft a description of their duties, authorities and responsibilities.
- Implement personnel checks to avoid giving discretionary authority to individuals who are on the OIG List of Excluded Individuals/Entities (LEIE). Conduct a check that reasonably determines whether the individual has a history of the conduct that shows a "propensity to engage in criminal, civil, and administrative violations".

- Evaluate the mechanism of disseminating policies and procedures and subsequent changes. Determine written evidence of dissemination of policies and procedures. Audit for compliance (e.g., if the written evidence is a signed statement by the staff that they have received and reviewed the information, is that signature in their personnel file). Establish mechanism to routinely assess staff comprehension (e.g., annual compliance test/refreshers, online quizzes, routine inquiries during rounds).
- Review/establish audit schedule including quality of care, billing and documentation audits. Develop protocol for post-audit action plan to address audit findings and evaluate for follow-through. Develop "safe" reporting mechanisms such as Compliance Hotline and anonymous online or physical mailboxes for reporting. Examine policies and procedure for language inclusive of anti-retaliation culture.
- Review/develop mechanisms to assess for compliance with policies and procedures and code of conduct. Establish discipline policy related to violation of standards. Establish routine audit activities for enforcement of the discipline policy.
- Develop/analyze mechanism to track compliance concerns. Review response to identified concerns for reasonableness and thoroughness. Analyze policy or procedure changes in response to identified concern, implemented to avoid repeat occurrence.
- Annually, or more often in early stages or as needed, review the compliance program, trending of compliance concerns, outcome of staff testing and audits, etc. and make necessary changes to support a culture of compliance at all levels in the organization.

A sample compliance action plan is provided on the Wroten and Associates website for your inspiration. In addition, a sample compliance issues tracking form is available as a springboard for your own tool, if your organization does not already have such a document.

About the author:

A senior associate returning to Wroten & Associates, Kimberli M. Poppe-Smart has unite her nearly 30-year nursing career with over a decade of legal experience into a health care risk management and compliance specialist. Her most recent experience as an appointed leader in state government, overseeing Medicaid, survey and certification and a myriad of additional state-administered program add a depth of knowledge and experience rarely seen in the litigation arena. Ms. Poppe-Smart earned a diploma in registered nursing in 1983, a bachelor of science in nursing in 1992 and graduated cum laude from Thomas Jefferson School of Law in San Diego, CA in 2002.

Ms. Poppe-Smart is a Wroten & Associates litigation team member as well as an expert in identifying and managing risks and implementing enterprise risk management plans and strategies. She has spoken nationally on health care topics including quality assurance, risk management and compliance.

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