



The Patient Protection and Affordable Care Act of 2010 ("PPACA") Includes Mandatory Compliance and Ethics Program Requirements for Nursing Home Providers

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Introduction

In March 2000, the Office of the Inspector General of the U.S. Department of Health and Human Services (the "OIG") published compliance program guidance for nursing facilities setting forth seven elements of an effective compliance program and discussing risk areas that providers should focus on.¹ In September 2008, the OIG published supplemental compliance program guidance for nursing facilities setting forth additional

risk areas for nursing home providers.² Each of these OIG guidance documents were published to assist providers with voluntary compliance program development.

Ever since the OIG guidance, compliance programs for healthcare providers were an entirely voluntary endeavor. However, new statutory provisions³ in the Patient Protection and Affordable Care Act of 2010, H.R. 3590 ("PPACA") have changed that. PPACA includes two separate mandatory requirements that apply to nursing homes providers that overlap but are not necessarily consistent.

Additionally, at least one of the requirements, in §6102, has a specific implementation timeline, and nursing home providers should not get confused by Centers for Medicare and Medicaid Services' ("CMS") recent solicitation for comments in the Federal Register.

The Compliance Program Requirements in PPACA

In §6401, PPACA requires the Secretary of the Department of Health and Human Services ("HHS") to implement requirements that providers and suppliers establish compliance programs as a condition of Medicare enrollment. HHS, in consultation with the OIG, is required to establish core elements for a compliance program for providers or suppliers within a particular industry or category. While the statute requires HHS to consider "... the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category", there is no specific implementation timeline for HHS under §6401. CMS has, however, solicited comments from the public as recently as February 2, 2011⁴ on several issues relating to its implementation of the core elements. At the moment, it is not clear how soon CMS will implement these requirements as well as the timeline for providers and suppliers.

CMS has taken the lead in implementing both of the mandatory compliance program requirements in PPACA. Importantly, CMS has acknowledged in recent regulatory pronouncements that the two provisions in PPACA relating to compliance programs overlap⁵ in their application to nursing homes. However, §6401 does not have statutory requirements for the core elements of a program. As discussed below, §6102 includes specific requirements. As a result, CMS has commented that it will work to ensure that regulations promulgated under each section do not conflict. In its proposed⁶ rule last September 2010 and its recent final rule in February 2011 relating to implementation of §6401, CMS commented that it "intends to establish compliance program core elements per Section 6401(a) of the ACA for NFs and SNFs that closely match the required components of a compliance program per section 6102 of the ACA."⁷

As mentioned, distinct from §6401, PPACA, in §6102, includes mandatory requirements for nursing home providers to have a compliance and ethics program in place that is effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care consistent with regulations developed by the HHS, working jointly with the OIG.

§6102 provides that the compliance and ethics program regulations must be promulgated not later than two years after the enactment of PPACA. The regulations "may" include a model compliance program and, with respect to specific elements of the program, "shall" vary with the size of the operating entity for organizations that operate five or more facilities. Each nursing home must have a compliance and ethics program in operation by March 23, 2013. The program must be "effective in detecting and preventing criminal, civil, and administrative violations" and "in promoting quality of care."

Although, §6102 does not require that the implementing regulations contain a model compliance program, different from §6401, this section specifies certain required components⁸ of a compliance and ethics program, including -

- Compliance standards and procedures for employees and other agents "that are reasonably capable of reducing the prospect" of criminal, civil, and administrative violations under the Act.
- The assignment of overall compliance program oversight to "high-level personnel" with "sufficient resources and authority" to assure such compliance.
- The exercise of "due care" not to delegate "substantial discretionary authority" to individuals whom the nursing facility knew or should have known had a "propensity to engage in criminal, civil, or administrative violations."
- The effective communication of compliance standards and procedures to all employees and agents.
- The adoption of monitoring and auditing systems reasonably designed to detect compliance violations by employees and other agents and a mechanism for employees and agents to report violations without fear of retribution.
- The consistent enforcement of appropriate disciplinary mechanisms, including for failure to detect an offense.
- Following detection of an offense, reasonable responses to include steps to prevent further similar offenses, including any modifications to the compliance program.
- The periodic reassessment of its compliance program to identify modifications necessary to reflect changes within the nursing facility organization.
- The mandatory components of a compliance and ethics program listed above are substantially similar to the elements contained in OIG guidance and Chapter 8 of the United

State Sentencing Commission's 2010 Federal Sentencing Guidelines Manual relating to the sentencing of organizations.

CMPs and Compliance and Ethics Programs

CMS also recently took the opportunity to link the implementation of compliance and ethics programs under §6102 to its implementation of other requirements relating to nursing homes in PPACA. On March 18, 2011, CMS implemented its final rule on civil monetary penalties for nursing home providers⁹ making certain changes required by §6111 of PPACA. In its discussion of possible reductions of civil money penalties (CMPs) when a provider self-reports and promptly corrects quality issues, CMS commented that its new authority to reduce CMPs in that circumstance works "in harmony with section 6102 of the Affordable Care Act that requires nursing homes to implement an effective ethics and compliance program...."¹⁰ Essentially, CMS expects that compliance and ethics programs in nursing homes will identify and correct issues and that identification and correction process can be used effectively to achieve a reduction in applicable CMPs via self-reporting the issue to CMS.

Conclusion

The major issue for nursing homes now is that the implementation of a compliance and ethics program is mandated by statute. Additionally, nursing homes should be on the look out for the implementing regulations. While they won't differ substantially from the statutory requirements, they are going to be helpful guidance.

Nursing home providers that developed a compliance plan in the past but did not fully implement it, need to pull that plan off the shelf, dust it off, review it and get it ready for effective implementation. Nursing home providers that have not already developed a program should begin the process now, taking into account the size and operations of their specific organization. Due to the implementation timing in §6102, nursing homes are likely going to see the implementation of regulations much sooner than for any other provider or supplier type. It is clear that the era of voluntary compliance programs is over.

1 65 Fed. Reg. 14289

2 73 Fed. Reg. 56832

3 H.R. 3590, Sec. 6102 and Sec. 6401

4 76 FR 5862 at 5942

5 76 FR 5862 at 5942

6 75 FR 58204 at 58227

7 76 FR 5862 at 5942

8 H.R. 3590, Sec. 6102

9 76 FR 15106

10 76 FR 15106 at 15110

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