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

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In March 2000, the Office of the Inspector General ("OIG") published compliance program guidance for nursing facilities setting forth seven elements of an effective compliance program. *65 Fed. Reg. 14289*. In September 2008 the OIG published supplemental compliance program guidance for nursing facilities setting forth risk areas for nursing home providers. *73 Fed. Reg. 56832*. Each of these OIG guidance documents were published to assist providers with voluntary compliance program development.

Now, The Patient Protection and Affordable Care Act of 2010, H.R. 3590 (the "Health Reform Bill") includes statutory provisions **requiring** nursing home providers ("Provider") 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 Secretary of the Department of Health and Human Services, working jointly with the OIG.

Title VI, Subtitle B, Part 1 of the Health Reform Bill provides that the compliance and ethics program regulations must be promulgated not later than 2 years after the enactment of the Health Reform Bill.

The term 'compliance and ethics program' is defined in Section 6102, as a program that:

(A) has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care; and

(B) includes at least the required following components:

(1) The Provider 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.

(2) Specific high-level employees must be assigned overall responsibility to oversee compliance with such standards and procedures and have sufficient resources and authority to assure such compliance.

(3) The Provider must use due care not to delegate substantial discretionary authority to individuals whom the Provider knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations.

(4) The Provider must take steps to effectively communicate 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 Provider must take 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 by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents can report violations by others within the organization without fear of retribution.

(6) The standards must be consistently enforced through appropriate disciplinary mechanisms, including, discipline of individuals responsible for the failure to detect an offense.

(7) After an offense has been detected, the Provider must take 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.

(8) The Provider must periodically undertake reassessment of its compliance and ethics program to identify changes necessary to reflect changes within the organization and its facilities.

This compliance and ethics program mandate is significant in that compliance programs for nursing homes will now be required by statute and regulation. Nursing Home Providers that have not already done so will want to begin the process of establishing a compliance and ethics program, taking into account the size and operations of their specific organization. Those that have a compliance and ethics program in place will want to review it to make sure it includes the foregoing components.

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Additional Information

For more information on complying with the new compliance and ethics program requirements or the Health Reform Bill in general, please contact a member of Benesch's Health Care Department. Contact information can be found at www.beneschlaw.com or by calling 216.363.4500.

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