
The 2010 Proposed Amendments to the Federal Sentencing Guidelines Help Companies Withstand Judicial Scrutiny Through Proactive Approaches to Corporate Compliance Programs

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For those of you who are unaware, the Federal Sentencing Guidelines for Organizations (“Sentencing Guidelines”) allow organizations to mitigate sentences if they can demonstrate adherence to 7 elements that demonstrate an effective compliance program. The 7 elements are also the underpinning of the Office of Inspector General’s (OIG’s) various compliance guidelines, including the OIG’s Compliance Program Guidance for Pharmaceutical Manufacturers, issued in April 2003, and the compliance programs that the majority of pharmaceutical companies have enacted.

Undoubtedly, the Sentencing Guidelines are riddled with ambiguities that make it difficult for a company to establish a compliance program that holds up to judicial scrutiny, and corporations rarely qualify for downward departures. Downward departure(s) is a term used in criminal law to refer to departing downward from the applicable sentencing guideline range for a statutory minimum sentence. The corporate compliance tide will soon turn as the Proposed Amendments of 2010 (“2010 Amendments”) directly implicate the relationship between a corporation’s Chief Compliance Officer (CCO) and the board of directors, and the manner in which a corporation should respond to the discovery of criminal conduct. The 2010 Amendments concern several areas, including reporting to the board, restitution and records management. In sum, the 2010 Amendments:

1. Enhance the reporting obligations from a CCO to the board of directors in order for the compliance program to be deemed effective in all circumstances;
2. Clarify the steps a corporation must take to meet the requirement for proper remediation in the event criminal conduct occurs;
3. Reject the proposed language that would have mentioned, for the first time, the appointment of monitors as a possible component of the remediation requirement or, separately, as a possible condition of probation for a convicted corporation; and
4. Reject language under consideration that would have given document retention policies unique prominence in the list of compliance program requirements.

Notably, for the first time, the 2010 Amendments will allow a corporation to receive a three level downward departure in sentencing for maintaining an effective compliance and ethics program, even where high level or substantial authority personnel

are involved in the offense, as long as the following conditions are met:

1. The individual(s) with “operational responsibility for the compliance and ethics program” (usually the CCO) must have had “direct reporting obligations” to the governing authority (usually the board of directors) or an appropriate subgroup thereof (e.g., an audit committee of the board of directors);
2. The compliance and ethics program must have detected the offense before discovery outside of the corporation or before such discovery was reasonably likely;
3. The corporation must have promptly reported the offense to appropriate governmental authorities; and
4. No individual with “operational responsibility for the compliance and ethics program” must have participated in, condoned, or have been willfully ignorant of the offense.

A compliance officer has “direct reporting obligations” if the officer has express authority to communicate personally and promptly to the board on any matter involving criminal conduct or potential criminal conduct. Additionally, the compliance officer must communicate to the board of directors at least once a year regarding the implementation and effectiveness of the compliance and ethics program.

The 2010 Amendments also elaborate on a corporation’s responsibilities after it has discovered criminal conduct. After the discovery of an offense, an effective compliance and ethics program requires that the corporation take reasonable steps to remedy the harm resulting from the criminal conduct. These steps may include: (a) providing restitution to identifiable victims; (b) self-reporting criminal conduct to relevant governmental authorities; and (c) cooperating with those governmental authorities. The list is not exhaustive.

After the discovery of criminal conduct, a corporation must assess its current compliance and ethics program and make appropriate modifications as required. I recommend, for example, that compliance programs (newly established or revisions to old) going forward have Standard Operating Procedures (“SOPs”) in place where the CCO has “direct reporting obligations” to the governing authority (usually the board of directors) or an appropriate subgroup thereof (e.g., an audit committee of the board of directors). Specifically, provisions of the appropriate SOPs should be clear that the CCO has “express authority to communicate personally” and promptly to the board on any matter involving criminal conduct or potential criminal conduct. Additionally, the SOPs must require the CCO to communicate to the board of directors at least once a year regarding the implementation and effectiveness of the compliance and ethics program.

The existence and adequacy of a corporation's pre-existing compliance program is a significant consideration when a prosecutor is considering whether to charge an organization. Notably, the 2010 Amendments encourage companies to be proactive through the engagement and retention of an outside professional advisor to ensure adequate assessment and implementation of any modifications to the corporation's compliance and ethics program. I strongly encourage those companies operating without a formal compliance and ethics program in place, and those companies that do have a formal compliance and ethics program in place, to retain an outside professional advisor to conduct a global risk assessment, assist with the implementation of a formal compliance and ethics program, and provide ongoing monitoring, training and comprehensive audits to ensure systematic and preventative measures are in place.

The 2010 Amendments will become effective November 1, 2010 unless Congress takes affirmative action to block them. So far, it does not look like Congress will be taking any action at all.

ⁱ See <http://www.ussc.gov/guidelin.htm>.

ⁱⁱ <http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>.

ⁱⁱⁱ See November 1, 2010 proposed Amendments to the Sentencing Guidelines.

^{iv} See *id.*

^v *Id.*

^{vi} *Id.*

^{vii} See November 1, 2010 proposed Amendments to the Sentencing Guidelines.

^{viii} See *id.*

^{ix} *Id.*

^x *Id.*

^{xi} See November 1, 2010 proposed Amendments to the Sentencing Guidelines.

^{xii} See United States Attorneys' Manual, Principles of Federal Prosecution of Business Organizations, § 9-28.800 (2008).

^{xiii} See November 1, 2010 proposed Amendments to the Sentencing Guidelines.