



© 2010 American Health Lawyers Association

May 07, 2010 Vol. VIII Issue 18

## Important Changes To The Compliance Plan Guidelines

*By Michael W. Peregrine, Esq. and Joshua T. Buchman, Esq., McDermott Will & Emery*

Health lawyers should be aware of a new compliance/governance development applicable to all corporate participants in the healthcare sector, whether for-profit or nonprofit, publicly traded, privately held or charitable.

Specifically, the United States Sentencing Commission has recently adopted several substantive amendments to the standards for an "Effective Compliance and Ethics Program" contained in the Federal Sentencing Guidelines. These new amendments make several subtle but important changes to the construct of an "effective" plan, focusing in particular on (i) board reporting relationships of the chief compliance officer, and (ii) actions the organization should take following detection of criminal conduct. The full text of the amendments is contained in regulations published on April 29 online at [http://www.ussc.gov/2010guid/20100503\\_Reader\\_Friendly\\_Proposed\\_Amendments.pdf](http://www.ussc.gov/2010guid/20100503_Reader_Friendly_Proposed_Amendments.pdf).<sup>[1]</sup>

Given the board's compliance plan oversight obligations, as articulated in the seminal *Caremark and Stone v. Ritter* decisions,<sup>[2]</sup> health lawyers are well advised to brief their clients' audit and compliance committees on the implications of these important new amendments.

In relevant part, the Federal Sentencing Guidelines provide that a corporation convicted of a criminal offense is eligible to receive a reduced sentence if it had in place at the time of the criminal offense a compliance plan that contained the seven specific criteria set forth in Chapter 8B2.1 ("Effective Compliance and Ethics Program"). These criteria require the organization to:

- (i) establish standards and procedures to prevent and detect criminal conduct;

- (ii) assure that its senior board and executive leadership are knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the plan;
- (iii) use reasonable efforts not to include within the management team any individual the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance plan;
- (iv) take reasonable steps to communicate periodically and in a practical manner its compliance standards and procedures by conducting effective training programs involving board members, senior executives, management, employees and agents;
- (v) take reasonable steps to monitor and audit the effectiveness of the compliance plan (including but not limited to implementing a confidential whistleblower process);
- (vi) promote and enforce the compliance program throughout the organization, through the use of appropriate incentives and disciplinary measures; and
- (vii) take reasonable steps, once criminal conduct has been detected, to respond appropriately to the conduct and to prevent further similar conduct, including making changes to the compliance program as appropriate.

The real significance of the Guidelines, however, is their application beyond those very limited circumstances in which a corporation has actually been convicted of a criminal offense. For example, federal law enforcement authorities will often refer to the Guidelines when determining whether to criminally prosecute an organization at the conclusion of a criminal investigation, or to pursue the organization on civil grounds. The Guidelines also are likely to be considered by corporate governance regulators and private plaintiffs in determining whether to pursue the members of a governing board for breach of its Caremark-based compliance plan oversight obligations. As most health care lawyers recognize, it is for these and other reasons that the provisions of Chapter 8B2.1 are generally recognized as the "benchmark" of an "effective" organizational corporate compliance plan.

The Sentencing Commission's April 29 action serves to:

- Clarify in two respects the requirement that the organization implement reasonable remediation efforts once criminal conduct has been detected: first, taking steps to

remedy the harm caused by the criminal conduct, including (but not limited to) restitution, self-reporting, and cooperation with authorities; and second, conducting an assessment of the organization's existing compliance program, including modifications to the program as may be appropriate to prevent the occurrence of similar conduct. The amendment specifically refers to the use of outside professional advisors to ensure the adequacy of the assessment efforts. (see, new Application Note to Section 8B2.1(b)(7))

– Add a new provision that sets forth the circumstances in which the court should subtract 3 points from the (convicted) corporation's "culpability score" under the Guidelines if the organization maintained an effective corporate compliance plan at the time the criminal conduct took place. The Guidelines generally prohibit the 3 point reduction if members of senior management were found to be involved with, condoned or were willfully ignorant of the criminal activity. The new provision creates an important exception to this prohibition if the following four conditions are satisfied:

1. Significantly, the chief compliance officer has a "direct reporting obligation" to the board or subgroup thereof (e.g., the compliance or audit committee);
2. The compliance program detected the criminal conduct before it was discovered or was reasonably likely to be discovered outside of the organization (i.e., by regulators);
3. The organization promptly reported the offense to the government; and
4. No corporate compliance officers were involved with, condoned or were willfully ignorant of the criminal offense (see, new Section 8C2.5).

The new USSC Commentary to this amendment defines "direct reporting obligation" as one which provides the compliance officer with "express authority to communicate personally with the governing authority or appropriate subgroup thereof (e.g., the audit/compliance committee) (A) promptly on any matter involving criminal or potential criminal conduct, and (B) no less than annually on the implementation and effectiveness of the organization's compliance plan." This definition clearly describes a direct and personal reporting relationship that may go beyond those currently in place at many health care organizations.

The initially proposed amendments, issued on January 21, 2010, contained an additional amendment that emphasized as part of periodic compliance plan assessment the importance of making all employees, as well as senior board and executive leadership, aware of the organization's document retention policies. In response to several public comments that questioned the effects of such a criterion, the Sentencing Commission elected not to include this in the final amendments.

These new amendments are noteworthy for health lawyers to the extent that they:

- Serve as a reminder that the Sentencing Commission Guidelines' "Effective Compliance and Ethics Program" criteria remain living, breathing and subject to periodic modification;
- Are a clear indication that prosecutors and other government regulators consider a "direct report" requirement an important element of a compliance program and will consider its existence when deciding whether to charge organizations in criminal cases or pursue them in civil cases (including those involving breach of fiduciary duty);
- Are consistent with other new compliance plan developments, including the board compliance oversight requirements mandated in recent Department of Health and Human Services (HHS) Office of Inspector General Corporate Integrity Agreements, the increased willingness of the federal government to exercise its right to exclude individuals (including officers and directors) from federal healthcare programs, and recent health sector application by federal prosecutors of the strict liability "Responsible Corporate Officer Doctrine"; and
- Provide an opportunity to raise for internal discussion, where applicable, both (i) board access and reporting relationships involving other key executives (e.g., the general counsel and the chief financial officer); and (ii) the most appropriate degree of coordination between the general counsel and the compliance officer (without creating "conflict of interest" concerns by federal prosecutors/investigators).

It may also be useful to consider these new amendments in connection with Section 6401 of the Patient Protection and Affordable Care Act, which mandates that providers establish a compliance program that contains certain core elements to be defined by the HHS Secretary, in consultation with the HHS Inspector General.

When evaluating the effectiveness of a compliance plan, health lawyers also are encouraged to consider the U.S. Department of Justice's "Principles of Federal Prosecution of Business Organizations."<sup>[3]</sup> These principles contain a specific chapter dedicated to the discussion of compliance plan effectiveness criteria considered by the Department of Justice as part of evaluating whether to criminally prosecute a corporation. While not entirely parallel to the USSC Guidelines, the Department of Justice's Principles contain many useful criteria consistent with those Guidelines.

The new Guidelines have been submitted to Congress and automatically become effective if not disapproved by Congress before November 1, 2010. The United States Sentencing Commission is an independent agency in the judicial branch of the federal government. It

was organized in 1985 to formulate a national sentencing policy for the federal court system. The Sentencing Guidelines are intended to facilitate the sentencing discretion of the federal courts to help assure consistency in the sentencing of similar offenders who commit similar offenses.

---

[1] View a "Reader friendly" version at

[http://www.ussc.gov/2010guid/20100503\\_Reader\\_Friendly\\_Proposed\\_Amendments.pdf](http://www.ussc.gov/2010guid/20100503_Reader_Friendly_Proposed_Amendments.pdf)

[2] *In re Caremark, Inc. Derivative Litigation*, 698 A. 2d 958 (Del. CH. 1996); *Stone v. Ritter*, 2006 Del. LEXIS 597 (Nov. 6, 2006).

[3] U.S. Department of Justice, "Principles of Federal Prosecution of Business Organizations,"

[http://www.justice.gov/usao/eousa/foia\\_reading\\_room/usam/title9/28mcrm.htm](http://www.justice.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm).

© **2010 American Health Lawyers Association**

1620 Eye Street NW, 6th Floor

Washington, DC 20006-4010

Phone: 202-833-1100 Fax: 202-833-1105