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Changes to Compliance Plan Guidelines Focus on Reporting Relationships

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Substantive new amendments to the U.S. Sentencing Commission's (USSC) template compliance plan guidelines require the attention of health care counsel—and the board's corporate compliance committee. These new amendments make several subtle but important changes to the construct of an ''Effective Compliance and Ethics Program,'' 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 and available on line at *http://www.ussc.gov/2010guid/ finalamend10.pdf*.[1]

As most health lawyers know, these template guidelines serve as the foundation for the compliance plans of most health industry companies—whether they are for profit or nonprofit, publicly traded, privately held, or charitable in nature. Thus, any amendments thereto should be closely considered—especially given the board's compliance plan oversight obligations, as articulated in the seminal *Caremark* and *Stone v. Ritter*

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[1] ''Reader friendly'' version accessible at *http://www.ussc.gov/2010guid/20100503_Reader_Friendly_Proposed_Amendments.pdf*.

decisions.[2] In particular, these amendments represent the latest in a series of recent developments affecting the structure, implementation and board oversight of compliance programs.

Background

Section 8B2.1(a) of the Federal Sentencing Guidelines (as promulgated by the Sentencing Commission) provides generally that to have an effective compliance and ethics program for purposes of the determination of a favorable culpability score and probation conditions, an organization shall: (a) exercise due diligence to prevent and detect criminal conduct; and (b) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. In that context, an ''effective'' compliance program is one which is reasonably designed, implemented, and enforced as it relates to preventing and detecting criminal conduct. (The failure to prevent or detect a particular offense doesn't necessarily mean that a particular compliance program is not generally effective.) The seven minimal requirements for an ''effective plan'' are set forth in Section 8B2.1(b), and require an organization to:

1. Establish standards and procedures to prevent and detect criminal conduct;
2. Assure that both its governing body and its executive leadership are knowledgeable about the content and operation of the compliance and ethics program and exercise reasonable oversight with respect to the implementation and effectiveness of the plan;
3. Apply 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;
4. Take reasonable steps to communicate periodically and in a practical manner its compliance standards and procedures by conducting effective training programs involving (and otherwise disseminating information to) board members, senior executives, management, employees, and agents;
5. Take reasonable steps to monitor and audit the effectiveness of the compliance plan (including but not limited to implementing a confidential whistleblower process);
6. Promote and enforce the compliance program throughout the organization, through the use of appropriate incentives and disciplinary measures; and
7. 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.

Why the Guidelines Matter

For the vast majority of health care companies, the significance of the guidelines is not their application to those very limited circumstances in which a corporation actually has been convicted of a criminal offense. Rather, the guidelines' significance is their application by regulators to evaluate corporate conduct outside of (*i.e.*, way before) the sentencing process. For example, federal law enforcement authorities often will 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. That is why the Sentencing Commission's guidelines generally are recognized as the ''benchmark'' of an ''effective'' organizational corporate compliance plan—and why amendments to the guidelines should be given close attention.

The Focus of the Amendments

Generally speaking, the Sentencing Commission's April 29 action makes two particular changes to the guidelines regarding the sentencing of organizations.

First, the amendments provide encouragement (by means of a potential sentence mitigation) for an organization to adopt a reporting structure that assigns compliance and ethics officers direct reporting obligations to the organization's governing body. This is accomplished by adding 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 federal 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 commentary defines a direct and personal reporting relationship in such a manner that may exceed the relationship currently implemented by many health care organizations.

Second, the amendment clarifies the remediation efforts required of an effective compliance plan, by describing the reasonable steps an organization should

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

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take to respond appropriately after criminal conduct is detected and to prevent further similar conduct. These efforts include taking steps to remedy the harm caused by the criminal conduct, including (but not limited to) restitution, self-reporting, and cooperation with authorities. They also include 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 advisers to ensure the adequacy of the assessment efforts. (see, new Application Note to Section 8B2.1(b)(7))

What Was Left Out

As originally proposed on Jan. 21, the amendments also contained a series of provisions intended to emphasize the importance of document retention policies as part of an effective compliance plan. For example, one such provision would have clarified that management and the board should be aware of the organization's document retention policies and should make sure that such policies are designed to meet the goals of an effective compliance program. Another such provision would have required an organization (as part of periodic compliance plan assessment) to verify that all employees, as well as senior board and executive leadership, were aware of the organization's document retention policies. In response to several public comments that questioned the value of such requirements, the Sentencing Commission elected not to include these provisions in the final amendments.

The Significance of the 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. This is especially important to compliance committees, which should consider receiving a periodic briefing from the compliance officer and general counsel with respect to changes/updates to compliance plan standards from not only the USSC, but other relevant state and federal agencies as well (*e.g.*, Department of Justice, Department of Health and Human Services, state Medicaid agencies).

■ 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). While many organizations currently maintain some form of board reporting access for their compliance officer, query whether those relationships currently contemplate the explicit concept of a ''direct report'' relationship envisioned by the USSC.

■ Are consistent with a series of other new compliance plan developments, including:

(a) The board compliance oversight requirements mandated in at least six recent DHHS OIG corporate integrity agreements entered into over the last several years, all of which contain provisions requiring the chief compliance officer to report directly to the board or to the audit committee;

(b) The increased willingness of the federal government to exercise its right to exclude individuals (including officers and directors) from federal health care programs (see, *e.g.*, the Bernabe[3] and Oxycontin exclusions);

(c) State regulatory efforts (such as those of the New York State Office of Medicaid Inspector General) to hold provider governing boards directly accountable for compliance plan failures;[4] and

(d) Recent health sector application by federal prosecutors of the strict liability ''Responsible Corporate Officer Doctrine.''[5]

■ 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). This is especially important given the position of the DHHS Office of Inspector General that the chief compliance officer should not have a reporting relationship with the general counsel, for conflict of interest reasons.[6]

It also may 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 secretary of the Department of Health and Human Services, in consultation with the DHHS Inspector General. It is the authors' expectation that any such forthcoming ''definition'' will include elements that speak to each of (a) the board's compliance plan oversight obligations; (b) the direct reporting relationship of the compliance officer to the board/audit committee; and (c) the absence of a direct reporting relationship of the compliance officer to the general counsel.

When evaluating the effectiveness of a compliance plan, health lawyers are also encouraged to consider the Department of Justice's ''Principles of Federal Prosecution of Business Organizations.''[7] 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. The principles adopt a very practical approach to measuring compliance plan effectiveness, focusing in part on the role of management and the board in enforcing the program, the exercise of independent judgment by the governing board, and the commitment of adequate resources to

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[3] *http://oig.hhs.gov/publications/docs/press/2009/hhs_oig_bernabe_exclusion_release.pdf*.

[4] *http://www.omig.state.ny.us/data/images/stories/work_plan/omig_work_plan_2009_2010.pdf*.

[5] Peregrine and Buchman, ''Alerting the 'C-Suite'': The Responsible Corporate Officer Doctrine - AHLA In-House Counsel and Business Law and Governance Practice Groups (February, 2010).

[6] *http://oig.hhs.gov/fraud/cia/agreements/pfizer_inc_08312009.pdf*.

[7] 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.

plan implementation.[8] 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 Nov. 1. The U.S. 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.

[8] Peregrine and Coffey, The ''Filip Memorandum and Stein: Relevance to Healthcare Providers'' AHLA Business Law and Governance Practice Group (September, 2008).

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