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New Federal Sentencing Guidelines requirements for an effective compliance program

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Health care organizations face a daunting array of statutes and regulations, including the False Claims Act, federal and state anti-kickback statutes, self-referral prohibition, fraud and abuse laws, federal and state privacy and security laws including the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security requirements, corporate practice of medicine prohibitions, and licensing laws. In order to comply with these laws, most health care organizations have adopted compliance programs designed in accordance with the standards for an “effective” compliance program under the Federal Sentencing Guidelines (FSG).

The United States Sentencing Commission’s (USSC’s) recent amendments to its FSG Manual will have significant implications for health care organizations that are seeking to obtain leniency based on the maintenance of effective compliance programs. The amendments make important changes to the construct of an “effective” compliance program, focusing on: (1) board reporting relationships of the compliance officer; and (2) actions health care organizations should take following detection of criminal conduct. Unless overturned by Congress, the new amendments take effect on November 1, 2010.

The FSG requirements

The United States Sentencing Commission was organized in 1985 to develop a national sentencing policy for the courts. The FSG were developed to structure the courts’ sentencing discretion to help ensure that similar offenders who committed similar offenses would receive

similar sentences. The FSG are only advisory and courts are not bound by them; however, courts must take the FSG into account when sentencing, and a sentence within the Guidelines’ recommended range is presumptively valid.

Chapter Eight of the FSG sets forth the procedures for sentencing organization defendants and includes detailed instructions for determining: (1) how an organization should structure its compliance programs to receive credit at sentencing¹; (2) how to determine the amount of the organization’s criminal fine²; and (3) the conditions under which it would be appropriate to sentence an organization to a term of probation.³ The recent amendments change aspects of each of the referenced sections of the FSG.

Section 8C of the FSG assigns a culpability score to the organization based on the size of the company, management level within the company at which the crime took place, and the effectiveness of the compliance program. Under the Guidelines, an organization’s culpability score is lowered significantly if it has an “effective” compliance program, as defined in the FSG. The Guidelines provide the framework for the imposition of criminal punishment—and, as a practical matter, often guide the government and parties in discussions about resolving criminal investigations.

For example, the Justice Department’s corporate charging policies and principles of federal prosecution (both outlined in the U.S. Attorneys’ Manual) instruct federal prosecutors to consider the FSG in deciding whether to charge a corporation and which charges to select.⁴ Three of the nine corporate charging principles set forth in the U.S. Attorneys’ Manual focus on compliance programs. In fact, the manual specifically instructs prosecutors to ask the following questions:

- Is the corporation’s compliance program well designed?

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- Is the program being applied earnestly and in good faith?
- Does the corporation's compliance program work?⁵

Currently—that is, before the just-proposed FSG amendments go into effect in November—the Guidelines provide that an effective compliance program shall meet the criteria set forth below:

To have an effective compliance and ethics program ... 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.⁶

To achieve this result, the FSG encourage affirmative measures, such as the conduct of due diligence, reasonable oversight by the organization's governing authority, delegation of compliance responsibilities to specific individuals who have day-to-day operational responsibility for the compliance program, effective training programs, and auditing.⁷ The FSG further "minimally require" that organizations take the following seven steps to establish an "effective" compliance program:

1. Establish standards and procedures to prevent and detect criminal conduct.
2. Governing authority (the board of directors) should be knowledgeable about the context and operation of the compliance program, and should exercise reasonable oversight with respect to the compliance program.
3. Take reasonable efforts to exclude from substantial authority personnel any individual that it knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance program.
4. Take reasonable steps to communicate periodically and in a practical manner to its workforce its standards and procedures and other aspects of the program by conducting effective training programs and disseminating information appropriate to the respective roles/responsibilities of individuals.
5. Take reasonable steps to ensure that the program is followed, including monitoring and auditing to evaluate the effectiveness of the programs, and to detect criminal conduct, and have and publicize a system for the workforce to anonymously or confidentially seek guidance regarding potential criminal conduct without fear of retaliation.
6. Promote and enforce the program consistently through appropriate incentives to comply, and through appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.

7. After criminal conduct has been detected, take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the compliance program.⁸

A health care organization that has properly adopted and implemented the seven features noted above has a greater chance of demonstrating that it has established a compliance program which will be deemed "effective" for the purposes of the FSG and will likely reduce its penalties in the event of a conviction. Leniency could mean lower fines and penalties or deferred prosecution in which governmental authorities agree to dismiss charges in exchange for certain actions by the health care organization, such as implementing a Corporate Integrity Agreement to prevent future wrongdoing.

Direct reporting structure for compliance officers

Generally, a health care organization receives no credit for maintaining an effective compliance program if members of senior management were found to be involved with, condoned, or were willfully ignorant of the criminal activity. The new amendments create an important exception to this general rule if: (1) the compliance officer has a "direct reporting obligation" to the board or a subgroup of the board (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 by regulators or other persons outside of the organization; (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.⁹

A "direct reporting obligation" is defined as one which provides the compliance officer with express authority to communicate personally with the board promptly on any matter involving criminal or potential criminal conduct, and no less than annually on the implementation and effectiveness of the organization's compliance plan.¹⁰

The new amendment demonstrates that the government considers 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).

Remedial steps for compliance credit

The amendments would also require organizations to take steps to remedy the harm caused by violations, including making restitution to

identified victims. The amendment sets up two phases of remediation required in order to receive credit. First, a health care organization must make reasonable efforts to remedy the harm that has taken place and, second, the health care organization must revise its compliance program to prevent similar criminal conduct in the future.

To remedy the harm, the amendment states that a health care organization should take “reasonable steps, as warranted under the circumstances, to remedy the harm resulting from the criminal conduct.” According to the USSC, this “may include, where appropriate, providing restitution to identifiable victims, as well as other forms of remediation.”⁶ The Commission adopted this permissive language in response to concerns raised in the written comments that restitution may not always be appropriate, even when there are identifiable victims—such as when restitution might operate as an admission in a parallel proceeding. The amendment further notes that “[o]ther appropriate [remediation] responses may include self-reporting, cooperation with authorities, and other forms of remediation.”¹¹

Further, the health care organization should respond appropriately to the criminal conduct and prevent further similar misconduct by making any necessary modifications to the organization’s compliance program and retraining staff with regard thereto. A health care organization may also decide to retain an independent monitor to ensure adequate implementation of such modifications. This amendment is important because it clarifies steps that health care organizations should take after detecting criminal conduct in order to remedy the resulting harm and to prevent future criminal conduct.

Use of outside advisors

The USSC had initially proposed changes that would have increased the use of independent monitors. In response to concerns regarding the potential overuse of monitors, the Commission adopted language stating that the steps an organization takes to prevent future similar criminal conduct “may include the use of an outside professional advisor to ensure adequate assessment and implementation of any modifications [to the compliance and ethics program].”¹²

In determining when to seek independent advisor review of compliance program modifications, health care organizations should consider: (1) the severity of the compliance violation; (2) the level and number of personnel allegedly involved in the wrongdoing; (3) the magnitude and complexity of the recently imposed compliance program revisions, and whether an outside advisor would add related expertise; and (4) the extent to which the health care organization anticipates staff resistance

to proposed compliance program modifications, and whether or not an independent advisors may be helpful in ensuring implementation.

Conclusion and recommendations

The new amendments highlight the importance of comprehensive and effective compliance programs, and provide written guidance on how to structure compliance programs to favorably affect sentencing decisions. The amendments provide a clear indication that government regulators consider a “direct report” requirement an important element of a compliance program and will consider its existence when deciding whether to charge health care organizations in criminal or civil cases. The amendments also reflect what the USSC considers to be an appropriate organizational response, once criminal conduct has been detected.

A health care organization can consider a number of practical steps if it decides to structure its compliance program to be consistent with the recent FSG amendments:

■ Consider modifications to your compliance officer organizational reporting structure.

In light of the new amendment, health care organizations should re-examine and, if necessary, redefine the role of the compliance officer with respect to board access and reporting relationships, as well as the most appropriate degree of coordination between the compliance officer and other key senior executives. In order to receive favorable consideration, the compliance officer must promptly report allegations and must give regular reports directly to the board of directors. A health care organization in which the compliance officer reports to the general counsel or to a corporate officer, rather than the board or a committee of the board will be considered an ineffective structure under the new Guidelines.

■ Document the compliance officer reporting structure and duties.

Document the compliance officer’s authority to bring matters to the attention of the board or applicable board committee in the compliance program policies and procedures and in the compliance officer’s job description.

■ Educate the board of directors and define the board’s role in compliance.

The board should be briefed on the implications of the new amendments to the FSG. It is also important to define the board’s role in compliance, and to identify a board member or board committee as

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the responsible board representative for compliance issues. The board should provide reasonable oversight of the compliance program.

■ **Investigate all compliance issues raised.**

If a potential problem is brought to the attention of responsible persons, it should be investigated promptly, and the findings related thereto should be reported to the board or its designee.

■ **Develop and maintain tools to measure the effectiveness of the compliance program.**

Periodic risk assessments and review of the compliance program elements should be designed to evaluate and improve compliance program effectiveness, taking into account relevant developments and health care industry standards.

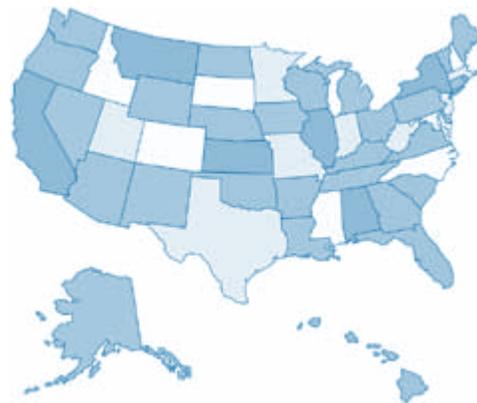
■ **Take meaningful remedial action.**

Health care organizations that are currently reviewing or handling

evidence of misconduct should address remediation and future effectiveness. When allegations of wrongdoing arise, the compliance officer should promptly report the conduct to the board of directors or board committee. The board or board committee should then evaluate the involvement of any high-level personnel and address with the compliance officer the proper remedial steps including, under the right circumstances and in consultation with counsel, the merits of self-reporting. Once criminal conduct has been verified, the health care organization should take steps to understand how it occurred and put in place measures to detect or prevent recurrence, which may include use of an independent outside advisor. ■

1. U.S. Sentencing Guidelines Manual Section 8B2.1
2. U.S. Sentencing Guidelines Manual Section 8C.
3. U.S. Sentencing Guidelines Manual Section 8D.
4. U.S. Attorneys Manual Section 9-28.300(a)(5), (A)(6), www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/28micrm.htm#9-28.300.
5. *Id.* at Section 9-28.800.
6. U.S. Sentencing Guidelines Manual Section 8B2.1(a).
7. U.S. Sentencing Guidelines Manual Section 8B2.1(b).
8. *Id.*
9. U.S. Sentencing Commission, Amendments to the Sentencing Guidelines at 17-18 (April 30, 2010) [hereinafter referred to as "Amendments"], available at <http://www.uscc.gov/2010guid/finalamend10.pdf>. 10. *Id.*
11. Amendments, *supra* n note 1, at 17.
12. *Id.*

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