

**MAR 18 2010**

Michael Courlander
Public Affairs Officer
United States Sentencing Commission
One Columbus Circle, NE
Suite 2-500
Washington, DC 20002-8002

RE: Proposed Amendments to Sentencing Guidelines

Dear Mr. Courlander:

In response to the January 21, 2010, Federal Register Notice, 75 Fed. Reg. 3525, published by the United States Sentencing Commission (Commission), the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) is submitting comments to the proposed amendments to the Federal Sentencing Guidelines for United States Courts.

A. The Office of Inspector General

The mission of the OIG, as mandated by Public Law 95-452 (as amended), is to protect the integrity of HHS programs, as well as the health and welfare of the beneficiaries of those programs. The OIG's duties are carried out through a nationwide network of audits, investigations, inspections, and other mission-related functions performed by OIG components.

As one of our functions, the OIG develops and monitors corporate integrity agreements (CIA) with individuals and entities. In the context of organizations, the CIA requires a framework within which an entity can create a compliance program tailored to its business model and designed to prevent future fraud, waste, and abuse of Federal health care programs. Generally, the OIG monitors the entity's operations, including its compliance program and billing practices, typically for a period of five years. In most cases, the entity is required to engage an independent auditor to evaluate its compliance with Federal health care program requirements annually. In certain cases, the OIG appoints an independent quality monitor to ensure the entity's compliance with medically-recognized standards of care.

The OIG has been monitoring CIAs with a variety of types of health care providers since 1998. In evaluating the qualifications of independent monitors, the OIG's expertise with the relevant regulatory and programmatic issues is crucial. Among other factors, the OIG must consider the nature of the engagement, the scope of the work, and the program in which the entity operates in order to ensure that the independent monitor's work product is useful and appropriate.

B. Proposed Modifications

The OIG's comments relate to the Commission's proposal that allows appointment of an independent corporate monitor as a condition of probation under section 8D1.4. The OIG commends the Commission for its recognition that independent corporate monitors can provide valuable oversight of an organization that is in the process of reshaping its compliance with the law. The OIG suggests, however, that with minor modifications to the proposed language, the Commission can include federal agencies as partners in the monitor selection process and thereby provide a valuable resource to the courts and probation officers.

The OIG recommends a modification to section 8D1.4 in three areas. Section C of this letter contains the text of the proposed modifications.

1. Require the sentencing court to consider the views of appropriate government agencies during the selection of an independent corporate monitor.

To improve the transparency and integrity of the monitor selection process, the OIG recommends that the Commission modify the text of section 8D1.4(b)(3) to specifically state that the court has approval authority of the independent monitor. The text of section 8D1.4 limits the selection of the independent corporate monitor to the parties (the defendant and prosecution) or, in the absence of such an agreement, the court. Compare Proposed Section 8D1.4(b)(3) with Application Note. Because the defendant is the subject of the monitoring and must also bear the costs associated with monitoring, the defendant may not be incentivized to select a truly independent monitor who will conduct a thorough review. The prosecution, while highly motivated to identify an independent monitor, may lack sufficient familiarity with potential qualified candidates to select the most appropriate monitor.

Moreover, to further enhance guidance available to the court, the OIG recommends that the Commission direct the sentencing court to consider the views of government agencies in the selection process. Often times, the government agency may be in a better position to evaluate potential monitors within the private sector who assert expertise and experience in the programs at issue. In addition, the government agency's oversight of

the affected programs can add focus and efficiency to the selection process as a result of its regulatory expertise. When read in context with the text of section 8D1.4, the proposed revision to the Application Note for section 8D1.4 creates some ambiguity as to whether the government agency should be consulted on all conditions of probation or only a subset.

2. Clarify the scope of work to be performed by the independent corporate monitor.

As currently drafted, the court approves the scope of work to be performed by the independent monitor. See Proposed Section 8D1.4(b)(3). Absent consultation with an independent expert, the court is unlikely to be presented with a comprehensive work plan for the independent corporate monitor. The defendant, who is the subject of the monitoring and must also bear the costs associated with monitoring, may not be incentivized to develop a comprehensive work plan. The prosecution may lack the regulatory expertise to develop an appropriate monitoring framework.

The proposed text of the Guidelines also provides little guidance for the court, with just a single example of work to be completed by the independent corporate monitor. See Proposed Section 8D1.4(b)(6). Specifically, section 8D1.4(b)(6) states that the organization shall be subject to “unannounced examinations of its books and records at appropriate business premises by the probation officer, or experts engaged by the court, or independent corporate monitor[.]” Two other suggestions are included in section 8D1.4(b)(6) but the independent corporate monitor is not listed as performing these tasks.

The Commission could enhance guidance provided to the sentencing court regarding the roles and responsibilities of the independent corporate monitor with two modifications. First, the Commission could clarify in the Application Note for section 8D1.4 to state that the court should consider the views of the government agency when evaluating the monitor’s work plan. Government agencies are familiar with federal program vulnerabilities and future potential areas of fraud, waste and abuse.

Second, if the Commission wants to provide specific examples of monitoring that can be done for an organization under probation, the Commission should clarify that monitors can perform any of the functions proposed in the new section 8D1.4(b)(6). In the OIG’s experience, an examination of documents (“books and records”) alone is insufficient to determine whether an organization is in compliance with the law. While it is important to review documentary evidence of compliance and compliance programs, an independent monitor must also interview individuals operating within the organization to supplement and confirm the books and records review. Also, an independent monitor needs the

authority to inspect an entity's facilities on a unannounced basis to get a full picture of the compliance and business operations on a day to day basis.

3. Include regulatory oversight authorities in the scope of government regulatory agencies that should be consulted.

The views of regulatory agencies are currently considered when determining the conditions of probation for an organization. Specifically, the current Application Note for section 8D1.4 states that the court should "consider the views of any governmental regulatory body that oversees conduct of the organization relating to the instant offense" with respect to the conditions of probation that the court should impose. The Application Note also states that the periodic reports submitted to the court or probation officer should be shared with the "governmental regulatory body that oversees conduct of the organization relating to the instant offense."

The OIG recommends that the Commission enhance the definition of "governmental regulatory agencies" in the proposed Application Note. The term should encompass both "operations" and "enforcement," as these functions are often housed in separate agencies. In some cases, it may be appropriate for either or both agencies to weigh in on the selection of the independent corporate monitor, the scope of the monitor's work, and other contemplated conditions of probation. Thus, the OIG recommends that the definition of "governmental regulatory agency" include both the regulatory body that oversees the organization's conduct (i.e., the agency that operates the Federal program in which the organization does business) and agencies with enforcement oversight of Federal programs.

C. Proposed Text of Section 8D1.4(b)

(b) If probation is imposed under Sec. 8D1.1, the following conditions may be appropriate:

* * *

(3) The organization shall be required to retain an independent corporate monitor agreed on by the parties and approved of by the court or, in the absence of such an agreement, selected by the court. The independent corporate monitor must have appropriate qualifications and no conflict of interest in the case. The scope of the independent corporate monitor's role shall be approved by the court. Compensation to and costs of any independent corporate monitor shall be paid by the organization.

* * *

(6) The organization shall submit to the following to be performed by the probation officer, experts engaged by the court, or an independent corporate monitor: (A) A reasonable number of regular or unannounced examinations of its books and records at appropriate business premises; (B) a reasonable number of regular or unannounced examinations of facilities subject to probation supervision; (C) interrogation of knowledgeable individuals within the organization; and (D) other tasks as deemed necessary to evaluate an organization's compliance with the law. Compensation to and costs of any experts engaged by the court or independent corporate monitors shall be paid by the organization.

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Application Notes

1. In determining the conditions to be imposed when probation is ordered under §8D1.1, including the qualifications and work plan of the independent corporate monitor, the court should consider the views of any governmental regulatory body, including the regulatory enforcement authority, that oversees conduct of the organization relating to the instant offense. To assess the efficacy of a compliance and ethics program submitted by the organization, the court may employ appropriate experts or require retention of an independent corporate monitor who shall be afforded access to all material possessed by the organization that is necessary for a comprehensive assessment of the proposed program. The court should approve any program that appears reasonably calculated to prevent and detect criminal conduct, as long as it is consistent with §8B2.1 (Effective Compliance and Ethics Program), and any applicable statutory and regulatory requirements. Periodic reports submitted in accordance with subsection (b)(4) should be provided to any governmental regulatory body that oversees conduct of the organization relating to the instant offense.

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In closing, thank you for your consideration of the OIG's comments. If you have any questions about our comments, please contact Susan Gillin at (202) 205-9426 or Catherine Hess at (202) 205-0573.

Sincerely,



Lewis Morris
Chief Counsel to the Inspector General