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October 7, 2002

VIA ELECTRONIC MAIL,
U.S. MAIL AND FACSIMILE

Mr. Michael Courlander
United States Sentencing Commission
One Columbus Circle, NE, Suite 2-500
Washington, DC 20002-8002

Re: U.S. Sentencing Guidelines for Organizations

Dear Mr. Courlander:

This letter is submitted in response to the Advisory Group on Organizational Guidelines to the United States Sentencing Commission's request for additional comments on whether the Sentencing Guidelines should be modified. We are submitting these comments on behalf of several of our firm's clients in the health care industry, such as hospital systems, physicians and physician groups, managed care companies, pharmaceutical and medical device manufacturers, and other ancillary services providers.

Set forth below are various of the questions raised in the Advisory Group's request for comments along with our response.

Question 1(a): *Should §8A1.2, comment 3(k)(2), referring to the oversight of compliance programs by high-level personnel, specifically articulate the responsibilities of the CEO, the CFO and/or other person(s) responsible for high-level oversight? Should §8A1.2, comment 3(k)(2) further define what is intended by "specific individual(s) within high-level personnel of the organization"?*

Response: We do not believe that the Sentencing Guidelines should delineate specific responsibilities for particular high-level personnel within the organization or further define individual(s) within high-level personnel related to health care organizations because:

- each company may be organized differently whereby similarly titled individuals may have different job responsibilities within their respective organizations;

- irrespective of job title, due to differences in experience, training and temperament, some individuals are better suited to oversee compliance than others; and

- different organizations have different numbers of employees and contractors and it would be imprudent to attempt to establish a "one-size fits all" approach to compliance.

Accordingly, it is important to allow organizations to maintain flexibility with respect to the particular personnel structure of their compliance programs.

Question 1(b): *To what extent, if any, should Chapter Eight specifically mention the responsibility of boards of directors, committees of the board or equivalent governance bodies of organizations in overseeing compliance programs and supervising senior management's compliance with such programs?*

Response: Given the substantial differences in which boards of directors may be organized, the Sentencing Guidelines should not provide further details about the responsibilities of either the boards and/or the various committees of the boards. As set forth below, §8A1.2, comment 3(k)(7)(I) addresses that smaller organizations may have less formality in how they develop a compliance program. Therefore, the role of the board of directors for a large organization composed of board members who do not otherwise serve as officers of the organization would be very different than the board of directors for a smaller, closely held corporation in which the Board otherwise consists of all of the high-level managers who otherwise are responsible for overseeing the compliance program functions. In small organizations, board oversight may be implicit in the operation of the organization's compliance program, even if not formally stated.

Question 1(d): *Should §8A1.2, comment 3(k)(3), which refers to the delegation of substantial discretionary authority to persons with a "propensity to engage in illegal activities," be clarified or modified?*

Response: We believe that this comment is deserving of additional clarity as organizations may struggle with what is meant for a person to have a "propensity" to engage in illegal activities.

- Does it mean that one has been convicted of a crime even if the crime was many years ago and/or unrelated to the individual's present duties?

- Does it only include felonies or also misdemeanors?

Therefore, further clarity on this issue would be beneficial to the extent it promotes flexibility for organizations to hire and maintain qualified employees who may have "youthful indiscretions" in their pasts.

Question 1(e): *Should §8A1.2, comment 3(k)(4), regarding the internal communication of standards and procedures for compliance, be more specific with respect to training methodologies?*

Response: There are numerous methods by which organizations communicate compliance standards to employees and other agents: live, in-person training sessions, video tape training sessions,

teleconferences, written exercises, interactive and/or web-based education sessions. Therefore, there is no single type of communication modality that has been proven to be most effective for every type of organization. The Sentencing Guidelines should provide organizations with sufficient flexibility in determining the most effective ways to communicate with their employees.

We also do not recommend modifying the language in the comment whereby the "or" would become an "and" in the examples of different forms of training and communication. By adopting this change, the Sentencing Guidelines would appear to be suggesting that written training programs are not appropriate and that training must be conducted using a different modality (e.g., in-person, live training). In light of the proliferation of interactive technology, we do not believe such a modification is appropriate.

Question 1(f): *Should §8A1.2, comment 3(k)(5), concerning implementing and publicizing a reporting system that fosters reporting without fear of retribution be made more specific to encourage: whistleblower protections, a privilege or policy for good faith self-assessment, the creation of a neutral or ombudsman office for confidential reporting, or some other means?*

Response: We believe that the Sentencing Guidelines sufficiently address this issue and that providing any further guidance on this would be superfluous. Moreover, the creation of an "ombudsman" office is duplicative in light of the role of the compliance officer and those individual(s) within high level management who are responsible for overseeing compliance as set forth §8A1.2, comment 3(k)(2).

Question 1(g): *Should greater emphasis and importance be given to auditing and monitoring reasonably designed to detect criminal conduct by an organization's employee and other agents, as specified in §8A1.2, comment 3(k)(5), including defining such auditing and monitoring to include periodic auditing of the organization's compliance program effectiveness.*

Response: We believe that the Sentencing Guidelines adequately address that a compliance program must ensure that sufficient auditing and monitoring occur.

We are concerned that to the extent the comments provide any additional emphasis on this issue, it will lead to a tacit requirement that organizations must engage outside auditors to conduct these reviews. Audits conducted internally may, in fact, be an effective means of conducting this type of monitoring.

Question 2: *While the Chapter Eight Guidelines currently provide a three-level decrease in the culpability score of organizations that are found to have implemented an "effective program to prevent and detect violations of law" should this provision be amended to provide an increase for organizations that have made no efforts to implement such a program?*

Response: We do not believe it is necessary to modify the Sentencing Guidelines because organizations that have not adopted an "effective" corporate compliance program will, in effect, have an increased culpability score in relation to organizations having compliance programs, as they otherwise will not be eligible for a decreased culpability score. To the extent an increase would be created, organizations with an effective compliance program not only would benefit from the three level decrease but they would also benefit from not having an increase level imposed. This could

potentially double the current effect on the culpability score of having a compliance program.

We further believe that by adding this provision, it would require organizations to prove that they have an "extraordinary" compliance program in order to qualify for the reduction in the culpability score, as mere compliance efforts alone may be viewed only as awarding the increase.

In addition, there may be legitimate reasons (e.g., the small size of an organization) that might justify not establishing a formal compliance program. By including an increase in culpability score when an organization has not established a compliance program, such organizations not only would not be able to benefit by a decrease in culpability, but would receive the "double whammy" of an increase in culpability.

Finally, while compliance programs should be encouraged, a "penalty" for not implementing a compliance program would be inappropriate, as lack of a compliance program should not be considered "misconduct" on the part of an organization.

Question 3: *How can the Chapter Eight Guidelines encourage auditing, monitoring, and self-reporting to discover and report suspected misconduct and potential illegalities, keeping in mind that the risk of third-party litigation or use by government enforcement personnel realistically diminishes the likelihood of such auditing, monitoring, and self-reporting?*

Response: The Chapter Eight Guidelines already encourage auditing, monitoring, and self-reporting as essential elements for an effective corporate compliance program. To the extent an organization does not engage in these activities, they otherwise would not be eligible for a decrease in culpability score as their program would not be "effective."

In the health care arena, the Department of Health and Human Services' Office of Inspector General ("OIG") has promulgated a Voluntary Disclosure Protocol whereby health care providers are encouraged to voluntarily disclose instances of potential fraud and abuse which may have given rise to corporate liability. (See 63 Fed. Reg. 58,402 (October 30, 1998).) Organizations participating in the Voluntary Disclosure Protocol have benefited from more favorable treatment in instances of Medicare billing infractions. Similarly the Guidelines could specify further benefits beyond a 3 point reduction in the culpability score. For instance, the culpability score could be reduced to zero if the conduct at issue was self-reported or restitution, without the imposition of a fine, could be permitted within the discretion of the court.

Question 4: *Are different considerations or obstacles faced by small and medium sized organizations in designing, implementing and enforcing effective program to prevent and detect violations of law. Does §8A1.2, comment 3(k)(7)(I) adequately address them?*

Response: Yes, small and medium size organizations face different obstacles. Although the first sentence of comment 3(k)(7)(I) adequately addresses these issues, the second sentence could be interpreted as stating that the only difference is in the degree of formality of the compliance program of a large organization versus a smaller one - that is, a larger organization should have established written policies defining the standards and procedures. However, this is only one, of many, differences, between large and small organizations' compliance programs. Therefore, the second

sentence should either be preceded with a statement indicating that it is only an example (i.e., by including "e.g.,") or should be modified to include other examples.

Question 4(a): *How frequently do small and medium sized organizations implement a corporate compliance program?*

Response: Although we are not aware of the statistics and frequency in which smaller organizations have adopted compliance programs, a number of our clients are small and medium sized organizations that have implemented compliance programs. In the health care industry, the OIG has encouraged all organizations, irrespective of size, to adopt a compliance program. In fact, in order to encourage smaller physician group practices to adopt compliance programs, the OIG issued Compliance Guidance specifically directed to that segment of the health care industry encouraging the adoption of a program with less formality than other large health care organizations (e.g., hospitals, clinical laboratories, etc.).

Question 5: *Should the provision of cooperation at §8C2.5, comment 12, and/or the policy statement relating to downward departure for substantial assistance at §8C4.1, clarify or state that the waiver of existing legal privileges is not required in order to qualify for a reduction either in culpability score or as predicate to a substantial assistance motion by the government? Can additional incentives be provided by the Chapter Eight Guidelines in order to encourage greater self-reporting and cooperation?*

Response: Yes, the Sentencing Guidelines should clarify that the waiver of existing legal privileges is not required in order to qualify for a reduction either in culpability score or as a predicate to a substantial assistance motion by the government. Waiver of legal privileges has been a significant issue in the development of the OIG's Voluntary Disclosure Protocol, with OIG initially taking a position requiring waiver, but then substantially modifying its position in order to encourage self-reporting. To the extent a clarifying statement were included in the Guidelines that waiver is not required, the issue could be affirmatively resolved for other segments of the industry. Preservation of legal privileges is an important public policy objective. Moreover, preservation of legal privilege will encourage self-disclosure, which in turn will foster settlements rather than protracted litigation.

As to additional incentives, see Response to Question 3 above.

Question 6: *Should Chapter Eight of the Sentencing Guidelines encourage organizations to foster ethical cultures to ensure compliance with the intent of regulatory schemes as opposed to technical compliance that can potentially circumvent the purpose of the law or regulation? If so, how would an organization's performance in this regard be measured or evaluated? How would that be incorporated into the structure of Chapter Eight?*

Response: Chapter Eight of the Sentencing Guidelines should not be modified or "clarified" so as to encourage compliance with "the intent of regulatory schemes as opposed to technical compliance that can potentially circumvent the purpose of the law or regulation." First, the regulatory scheme centering around the manner with which health care entities are paid by the federal health care programs is, in fact, a very technical area of law. Second, in health care, there are a number of laws and regulations that are extraordinarily broad and have been subject to various interpretations of the

"intent" requirement both by the regulatory agencies responsible for interpreting and enforcing the laws as well as by the courts. For example, there are a number of very technical exceptions and safe harbors to the Federal Health Care Program Anti-Kickback Statute (42 USC 1320-7b(b)) and organizations that structure transactions or financial relationships in order to satisfy the requirements of the exceptions or safe harbors should not be perceived as having "circumvented" the intent of the law.

Therefore, it would be inappropriate for an organization to be determined to be in violation of a law with which it is compliant based on the imposition of a wholly subjective standard of "intent." Compliance needs to remain an objective standard, and courts should be bound to enforce and interpret the laws without imposing moral judgment or subjective notions of ethical conduct.

* * *

We appreciate the opportunity to comment on the US Sentencing Guidelines for Organizations. Please feel free to contact us if you have any questions or require further information.

Sincerely,

David E. Matyas

Carrie Valiant