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Proposed rule alters HIPAA investigation of noncompliance, imposition of penalties

by Sheila Lynch-Afryl, JD, Contributing Editor

To simplify, clarify, and reduce the burden of the compliance procedures for covered entities, the compliance and investigation provisions of 45 C.F.R. Part 160, subpart C, which currently only apply to the privacy standards, would be applicable to all of the Health Insurance Portability and Accountability Act (HIPAA) rules under a proposed rule issued by the Department of Health and Human Services (HHS). In addition, a new subpart D will address the issuance of a notice of proposed determination to impose a civil money penalty (CMP), as well as identifying violations, determining the number of violations, and calculating CMPs.

Mandatory imposition of penalties. Under the proposed rule, if the Secretary finds that a covered entity has violated an administrative simplification provision, he or she is required to impose a penalty unless the entity establishes an affirmative defense. Similarly, when more than one entity has violated a provision, the Secretary must impose a penalty on each; however, the Secretary may exercise his or her discretion in investigating only one entity or imposing different penalty amounts on each entity.

Maximum penalties. The proposed regulations would establish maximum penalties of $100 for each violation and $25,000 a year for all violations of an identical requirement during a calendar year. The proposed regulation would not set minimum penalties. In determining the amount of the penalty, the Secretary would consider aggravating or mitigating factors, such as whether the violation caused physical harm or any history of prior offenses.

Administrative review of ALJ decisions. Concerned that different administrative law judges (ALJs) might decide the same issues differently, HHS proposed a process for administrative review of initial ALJ decisions that would achieve consistency in CMP decisions. An April 17, 2003, interim final rule made the decision of the ALJ the final decision of the Secretary, thus permitting a respondent to file a petition for judicial review. The proposed rule would make an ALJ decision the initial decision of the Secretary, which could be appealed to the Departmental Appeals Board within 30 days.

Proposed Rule, 70 FR 20224, April 18, 2005, ¶162,003

Letters to the Editor

The CCH Health Care Compliance team welcomes comments or questions regarding articles published in the CCH Health Care Compliance Letter. Send comments to Sharon Sofinski, Coordinating Editor, at sofinsks@cch.com. For more information about the CCH Health Care Compliance Portfolio visit our online store at http://health.cch.com.

AHIMA survey shows many facilities are HIPAA compliant

by Sheila Lynch-Afryl, JD, Contributing Editor

According to a recent survey by the American Health Information Management Association (AHIMA), the majority of facilities are significantly compliant with the HIPAA privacy rule, and many say they are on the road to full compliance with the HIPAA security rule by its April 21, 2005, implementation date.

Forty percent of the hospitals and health systems surveyed are fully compliant with the privacy regulations, compared with last year's 23 percent, and 91 percent of all respondents considered themselves more than 85 percent compliant. Four percent of respondents were less than 50 percent compliant, while the percentage in 2004 was 7 percent.

Difficulties with HIPAA privacy requirements. Although most respondents reported no or only slight difficulties with most of the privacy rule requirements, a few requirements inspired significant concern:

- the privacy requirement for accounting for disclosures;
- access and release of information to law enforcement, most of whom were not made aware of the HIPAA regulation before the compliance date;
- access and release of information to patients' relatives or significant others;
- information being released for research protocols;
- access and release of information for subpoenas versus court orders; and
- business association agreements.

AHIMA suggested that more education or refinement may be necessary in these areas.

Accounting for disclosures. Accounting for disclosures was also a top issue for all organizations in 2004. Sixty-seven respondents in the 2005 survey received no or only a few requests for an accounting. According to AHIMA, the high percentage of no requests underlines the inefficient aspects of this requirement, especially since many of the disclosures may be the result of state laws and would normally be expected during the process of receiving health care services. AHIMA has sought an amendment to the accounting for disclosures requirement from the National Committee on Vital and Health Statistics, but no change has been recommended.

> **"Seventeen percent of respondents described themselves as completely compliant with HIPAA security requirements."**

Training. Because training and education have been important concerns for privacy officers, the survey asked questions related to privacy training for new employees. Sixty-two percent of the respondents reported that new employee privacy training is done in-house by the privacy or education officer. For ongoing training for current employees, training methods varied considerably but included newspaper articles to prompt employees to remember to continue their privacy vigilance.

HIPAA security compliance. Seventeen percent of respondents described themselves as completely compliant with HIPAA security requirements, and 43 percent described themselves as 85 to 95 percent compliant. Twenty-six percent felt they were 50 percent compliant, and 12 percent thought they were less than 50 percent compliant.

According to AHIMA, the significant number of organizations responding at 50 percent or less compliance is not surprising since the survey was completed in January 2005, and the project can be completed quickly. Facilities that were not ready frequently cited a lack of resources and time.

A total of 1,140 individuals participated in the survey, 51 percent of whom were designated as either the security or privacy officer for their organization. With this survey, AHIMA sought to educate the public and the industry in issues that have been and will need to be addressed, and to maintain and increase public trust in a healthcare system that needs to maintain and protect personal health information to provide maximum benefits to patients.

CCH Chicago Bureau, April 20, 2005

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Unless otherwise noted, all paragraph references are to the CCH Health Care Compliance Reporter.

Antitrust

Chicago-area doctors' group settles FTC price fixing charges

by CCH Editorial Staff

A Chicago-area physicians' group (Evenston Northwestern Healthcare Corp.) has agreed to stop collectively bargaining on behalf of its members in order to settle FTC charges that the group violated the FTC Act by facilitating and implementing agreements among rival physicians to fix prices and other terms of dealing with health plans and other third-party payors and by refusing to deal with such payors except on jointly determined terms. The Commission alleged that such joint negotiations led to reduced competition and higher prices paid by health plans and other payors to the group's doctors.

If approved, the proposed consent order settling the claim would bar the group from entering into or facilitating any agreement between or among physicians to:

1. negotiate with payors on any physician's behalf;
2. deal, not deal, or threaten not to deal with payors;
3. designate the terms on which to deal with any payor; or
4. refuse to deal individually with any payor, including pacts to deal with a payor only through specified arrangements. The proposed order would reinforce these provisions by barring the group from facilitating any information exchanges regarding payor contracts and by prohibiting it even from attempting to engage in any of the actions prohibited under the order.

"The Commission alleged that such joint negotiations led to reduced competition and higher prices paid by health plans and other payors to the group's doctors."

The physicians' group and its parent healthcare corporation would not be prohibited from participating in a "qualified risk-sharing joint arrangement" or a "qualified integrated joint arrangement". Arrangements would qualify as "risk sharing" if their financial risks were split among participating physicians and any agreement containing reimbursement or other terms of dealing were reasonably necessary to obtain significant efficiencies. Arrangements would be "clinically-integrated" for purposes of the proposed order if all physician participants participated in active and ongoing programs to evaluate and modify their clinical practice programs and if any agreement containing reimbursement or other terms of dealing were reasonably necessary to obtain significant efficiencies.

The proposed order would settle only one count of the Commission's complaint concerning the healthcare corporation's acquisition of a hospital in Highland Park, Illinois. Review of the merits of charges that the acquisition itself was illegal and anticompetitive is currently pending before an administrative law judge.

CCH Chicago Bureau, April 14, 2005

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On The Front Lines

The new advisory role of the Federal Sentencing Guidelines after *Booker/FanFan*: What does it mean and how long will it last? (Part 1)

By Michael E. Clark

At a healthcare fraud conference last year, I compared the mounting difficulties involved with trying to help white-collar clients avoid prison terms because of the inflexible Federal Sentencing Guidelines with the problem that limbo dancers encounter when they cannot bend any lower to pass under the bar.[1] While the analogy was reasonably apt at the time, recent case developments have halted, and perhaps reversed (if only temporarily), the trend to increase the severity of punishment meted out for white-collar violations. The first part of this article will briefly retrace the development of the Federal Sentencing Guidelines and how they reduced federal judges' traditional discretion to fashion appropriate punishment for individuals and businesses convicted of crimes. The second part will examine what led the Supreme Court to recently hold that these once-mandatory and popular guidelines now are only advisory. Finally, the article will address the likely effects from the change to advisory guidelines upon the investigation and prosecution of white-collar cases—including what this means for corporate entities and their ongoing compliance efforts.

The Push for Determinate, "Truth-in-Sentencing" Guidelines

In the span of the past few decades, federal criminal law was dramatically transformed by the Sentencing Reform Act of 1984 ("SRA")[2] and by the Federal Sentencing Guidelines ("Guidelines") that this legislation spawned—a result fully intended by Congress. The manner in which this happened, as one commentator ably explained, is that "[t]hrough the SRA, Congress created a Sentencing Commission in the Judicial Branch . . . [to] develop Guidelines to limit judicial discretion. [Congress] . . . also mandated, with narrow exceptions, that district courts should follow the Commission's instructions."[3]

Although the Guidelines were simple enough to conceive in theory, the newly formed Sentencing Commission faced a far more difficult task. To draft and implement the Guidelines required the Commission to address the myriad of possible fact patterns that can be presented in thousands of federal crimes,[4] and to account for the varied backgrounds of different types of offenders (ranging from first offenders to recidivists). Consequently, the Guidelines system that the Commission finally developed and implemented, as summarized below, was unfortunately somewhat mechanistic and arcane:

> The Federal Sentencing Guidelines are . . . nothing more than a set of instructions for one chart—the Sentencing Table. The goal . . . is to arrive at numbers for the vertical . . . and horizontal . . . axes on the Sentencing Table grid, which . . . generate an intersection in the . . . grid. Each such intersection designates a sentencing range expressed in months. . .
>
> The criminal history calculation reflected on the horizontal axis of the Sentencing Table is a rough effort to determine a defendant's disposition to criminality, as indicated by the number and nature of his prior contacts with the criminal law. The basic unit of measurement in this calculation is prior sentences imposed for misdemeanors and felonies.
>
> The offense level reflected on the vertical axis of the Sentencing Table is a measurement of the seriousness of the present crime.[5]

Sentencing Inflation in the Federal Courts under the Guidelines

The Guidelines, as originally implemented, functioned much like the Internal Revenue Code, since they had graduated levels by which the punishment meted out would be progressively increased (as are taxes under the Internal Revenue Code) unless the proponent could establish the

applicability of various recognized offsets. After the Guidelines became effective in November 1987, they have been periodically revised, including amendments to increase the range of punishment applied to white-collar offenses.

This sentencing inflation under the Guidelines seems likely to have reached its zenith in early 2003, following the passage of the Sarbanes-Oxley Act.[6] As I have written elsewhere, as a consequence of Enron's implosion and other corporate scandals, Congress mandated in "Sections 805, 905, and 1104(a)(3) of Sarbanes-Oxley . . . [that] the U.S. Sentencing Commission ("Commission") . . . act within 180 days (by January 25, 2003) to increase the punishment for fraud and obstruction crimes involving publicly traded companies[.]" [7]

The sad case of Jamie Olis, as described in the passage below, illustrates just how far the applicable Guidelines' punishment range for white-collar offenses has increased over the years:

> Olis [was] a mid-level accountant at an energy company who (unlike two of his superiors) went to trial and was convicted of various fraud charges for having engaged in "income-smoothing" or "cookie-jar accounting"of the company's earnings history [in a misguided effort] . . . to help the company meet its earnings expectations. Although Olis received no financial benefit for his misguided efforts, he got 24 years' imprisonment (compared with his cooperative bosses, whose sentences were capped at a 5-year maximum under plea agreements). The sentence was largely due to the calculations of the "amount of loss."[8]

If Olis' sentence is upheld on appeal, he must serve about 17 years' imprisonment because offenders serve at least 85 percent of their Guidelines' sentences—without the possibility of parole (which was eliminated after the Guidelines took effect). Olis' lengthy punishment was largely mandated by the 2001 Economic Crime Amendments[9] —which effectively *quadrupled* the six-year term that he would have previously faced under the facts. Yet, as harsh as the 24-year sentence may seem, had Olis committed his acts after the post-Sarbanes-Oxley amendments took effect, he would have faced a term of 55 to 60 years, for which he would have to serve at least 46 years before release.

Promulgation of the Organizational Guidelines—and the Boom in Corporate Compliance[10]

Business entities convicted of federal criminal offenses[11] for conduct occurring after November 1991 are sentenced pursuant to the "Organizational Guidelines" (codified in Chapter Eight of the Sentencing Guidelines). The Commission's approach to constructing an appropriate scheme to punish businesses convicted of federal crimes was necessarily quite different from that for punishing individuals. One reason is that imprisonment is not an option for such artificial "persons." Therefore, in crafting the Organizational Guidelines, the Commission focused mainly on the amount of fines that could be imposed. It decided upon a "carrot and stick" approach of punishment and reward, after reasoning that organizations are basically amoral and will condone the violation of laws when doing so is cost-effective.[12]

Under the Organizational Guidelines, companies are threatened with *severe* financial punishment to deter violations, and are rewarded for their self-monitoring efforts, primarily through the use of compliance programs[13] along with the timely admission of responsibility following the discovery of wrongdoing, and full cooperation with government investigators. These incentives,[14] buttressed by the strong guidance that governmental agencies have given about what constitutes sufficient cooperation,[15] have changed how companies react to the threat of possible federal criminal charges.

Before the Organizational Guidelines took effect and federal agencies announced their policies about what companies must do to secure leniency, companies often would try to protect their officers and employees even if doing so meant that the company would be charged. After the Guidelines took effect, and government agencies communicated their heightened expectations about what is necessary to obtain leniency, there was a major shift in how companies would react to threatened investigations and prosecutions. Now, most companies will usually try to avoid criminal charges at all costs—even if doing so means helping the government to identify and convict key company officers and employees.

The Sixth Amendment Evolves: From Offense Elements to Sentencing Factors and Beyond

Federal courts have long recognized that Congress has the authority to define the conduct that constitutes criminal violations: "Ever since . . . *United States v. Hudson & Goodwin* [11 U.S. 32, 33 (1812)], Congress has held exclusive power to define crimes . . . [by describing] what "elements" must be indicted and proved to a jury, and what maximum punishment may be imposed after conviction."[16] "The power to define crimes includes the corollary power to establish the statutory limits for the punishment

that can be imposed for a violation. Before the Sentencing Guidelines took effect, a federal jury's guilty verdict *impliedly* authorized a federal judge to impose a sentence as high as the statutory maximum.[17] But once the Guidelines became effective, the Sixth Amendment's guarantee of a jury trial[18] in federal criminal cases became less clear since the Guidelines' authorized punishment range ordinarily controlled the length of most sentences imposed, so long as the sentences were *less* than the statutory maximum. Despite the constitutional right to a jury trial, federal trial juries ordinarily were not presented with, nor were they required to make findings about, sentencing evidence that a judge would often later consider in determining an offender's punishment under the Guidelines (because, in federal courts, juries have not been involved in making sentencing decisions)."

The Supreme Court tried to avoid having to address this nascent Sixth Amendment problem, until recently, by endorsing a semantic distinction about what constitutes the required *elements* of a federal offense (which must be proved to a jury beyond a reasonable doubt) and what are mere *sentencing factors* (which do not have to be proved to a jury and require only a preponderance of evidence).[19] Yet, as commentators have noted, the Court's distinction between these issues started becoming unworkable after its decision in *Apprendi v. New Jersey*,[20] which held that "[o]ther than the fact of prior conviction, any fact that increases the penalty for a crime beyond the prescribed statutory maximum must be submitted to the jury, and proved beyond a reasonable doubt."[21]

Michael E. Clark, a partner in Hamel Bowers & Clark LLP, a litigation boutique in Houston, TX, has extensive litigation experience, and has taught for the National Institute for Trial Advocacy (NITA) for almost a decade. Before entering private practice, Mr. Clark was a federal prosecutor for 10 years (and was the Criminal Division Chief of the U.S. Attorney's Office in the Southern District of Texas during the last four years of service); before that, he was a state prosecutor for five years. Mr. Clark is the Chair of the Publications Committee for the ABA Health Law Section and a Vice Chair of the Section's Healthcare Litigation & Risk Management Interest Group. He served as Editor-in-Chief of the "The Health Care Fraud & Abuse Newsletter" (published by Law Journal Newsletters, a Division of American Lawyer Media, Inc.), served on the editorial board and wrote a monthly column for "The Managed Care Law Strategist," and is serving on the editorial board for the "Business Crimes Bulletin,"also offered by the same publisher. Mr. Clark is board certified in criminal law (by the Texas Board of Legal Specialization and the National Board of Trial Advocacy) and a Fellow of the American Bar Foundation. He has been an adjunct Professor at the University of Houston Law Center, where he has taught Antitrust and Health Care, and has co-taught Regulation of Biomedical Research. In addition to his J.D., Mr. Clark has two LL.M. degrees (Taxation and Health Law). He has written chapters for Aspen Publishing's 2003, 2004, and 2005 Health Law and Compliance Updates ("Current Issues in Pharmaceutical Marketing," "Current Issues in Healthcare and Antitrust", "Current Issues in Clinical Research," and "Compliance and Governance Issues and Trends after Sarbanes-Oxley"); prepared a chapter for the forthcoming BNA/Health Law Section Managed Care Litigationbook ("Litigation Issues in Antitrust and Managed Care"); and will be the editor of a treatise being developed by BNA/Health Law Section—Pharmaceutical Research & Marketing Law: A Guide for Health Lawyers. Mr. Clark speaks and writes frequently about a variety of topics affecting businesses and professionals. He can be contacted at (713) 869-0557 or by email at mclark@hbctrial.com.

1 Michael E. Clark, *How Low Can You Go?: Federal Sentencing Guidelines and Criminal and Civil Damages*, Prepared for the FOURTEENTH ANNUAL NATIONAL INSTITUTE ON HEALTH CARE FRAUD 2004 (May 12–14, 2004), sponsored by the ABA Criminal Justice Section, Health Law Section, Center for Continuing Legal Education, and The National Association of Medicaid Fraud Control Units.

2 The SRA, set out in Title II of the omnibus COMPREHENSIVE CRIME CONTROL ACT OF 1984, PUB. L. 98-473, "overhauled the federal sentencing system. . . ". JoAnne O'Bryant, Congressional Research Service, Crime Control: The Federal Response (Updated March 5, 2003), *available at* www.policyalmanac.org/crime/archive/ crs_federal_crime_policy.shtml <Site last visited April 10, 2005.>

3 Roger Craig Green, "The Untimely Death (and Rebirth) of the Federal Sentencing Guidelines", GEORGETOWN L.J. (Spring 2005). (Internal notes omitted;*available at* http://papers.ssrn.com/sol3/ <Site last visited April 10, 2005.>

4 As former U.S. Attorney General Ed Meese wrote, quoting an influential member of Congress, "We federalize everything that walks, talks, and moves," said Senator Joseph R. Biden, Jr., Chairman of the Senate Judiciary Committee from 1986-1994."Unfortunately, this is not much of an exaggeration; there are well over 3,000 federal crimes today. And this . . . does not include the 10,000 regulatory requirements that carry criminal penalties." Edwin Meese, *Big Brother on the Beat:The Expanding Federalization of Crime*, 1 TEX. REV. L. & POL 1, 2-3 (Spring 1997). An ABA group found that over 40 percent of federal criminal laws were enacted in the past 30 years. *See* ABA Task Force on the Federalization of Criminal Law, *The Federalization of Criminal Law* (1998), at 7. *See also* John S. Baker, *Measuring the Explosive Growth of Federal Crime Legislation*, The Federalist Society for Law and Public Policy Studies (reporting that over 4,000 offenses codified in the U.S. Code carry criminal penalties, which represents a 33 percent increase since 1980); *available at* www.fed-soc.org/ Publications/practicegroupnewsletters/criminallaw/crimreportfinal.pdf <Site last visited April 10, 2005.>

5 Clark, *How Low Can You Go?—Federal Sentencing Guidelines and Criminal and Civil Damages*, at 1 (citing Frank O. Bowman, III, *Coping with "Loss": A Re-examination of Sentencing Federal Economic Crimes under the Guidelines*, 51 VAND. L. REV 461, 473 (1998)).

6 THE PUBLIC ACCOUNTING REFORM AND INVESTOR PROTECTION ACT (commonly known as the Sarbanes-Oxley Act of 2002 or "Sarbanes-Oxley") was enacted as PUB. L. 107-204, 116 STAT. 745 (2002).

7 Michael E. Clark, *Foundations of White Collar Law and Practice*, Course Materials for the THIRTEENTH ANNUAL NATIONAL INSTITUTE ON HEALTH CARE FRAUD 2003 (May 14, 2003), sponsored by the ABA Criminal Justice Section, Health Law Section, Center for Continuing Legal Education, and The National Association of Medicaid Fraud Control Units, at 25.

[8] Michael E. Clark, 11 BUS. CRIMES. BULL. No. 12, at 3 (Jan. 2005).

[9] A good overview of the various changes made to the Guidelines under the 2001 Economic Crime Amendments is provided by Bowman, *supra*, in *Coping with "Loss": A Re-examination of Sentencing Federal Economic Crimes under the Guidelines*, 51 VAND. L. REV. 461 (1998).

[10] This section of the article is from Michael E. Clark, *Corporate Compliance Programs: Privilege, Work Product and Words to Save Them*, materials prepared for an ABA Health Law Section Teleconference, entitled "Health Law Contracting is Expanding: Here's Your Drafting Toolkit" (February 17, 2005).

[11] The development of corporate liability for federal criminal violations began with *New York Central & Hudson River R.R. v. United States*, 212 U.S. 481, 29 S.Ct. 304 (1909), which held that a corporation and its officers could be held criminally responsible. The Court explained its rationale for allowing an artificial entity to be prosecuted: "We see no valid objection . . . why the corporation, which . . . only can act through its agent and officers, shall be held punishable . . . because of the knowledge and intent of its agents to whom it has entrusted authority to act . . . and whose knowledge and purposes may well be attributed to the corporation for which the agents act." "We see no valid objection . . . why the corporation, which . . . only can act through its agent and officers, shall be held punishable . . . because of the knowledge and intent of its agents to whom it has entrusted authority to act . . . and whose knowledge and purposes may well be attributed to the corporation for which the agents act." *New York Central & Hudson River R.R*, 212 U.S. at 495. Potential federal criminal liability for business entities approaches strict liability since companies can only act through their officers, directors, and agents—and companies are charged with the "collective knowledge" of these individuals' actions. Companies have been held directly liable for the conduct of their policymakers and, through principles of vicarious liability and respondeat superior, for their agents' conduct during an employment activity. *See, e.g.*, *United States v. A & P Trucking Co.*, 358 U.S. 121, 125, 79 S.Ct. 203, 206–07 (1958) (reinstating criminal charges filed against partnerships (as entities) for violating Interstate Commerce Commission regulations as to the safe transport of dangerous articles). In some cases, the results appear to be both unfair and counter-intuitive. *See, e.g.*, *United States v. Hilton Hotels Corp*, 467 F.2d 1000 (9th Cir. 1972) (upholding conviction of entity although the corporation not only forbade the charged conduct but had also tried to prevent its occurrence). *See also* Mary Beth Buchanan, *Effective Cooperations by Business Organizations and the Implications of Privilege Waivers,* 39 WAKE FOREST L. REV. 587, 589-90 (2004) ("It is well established that a corporation is vicariously liable under federal law for the criminal conduct of its agents acting within the . . . scope of their employment or authority if the agents intended, at least in part, to benefit the corporation. . . even though . . . [their] actions may have been contrary to corporate policy. . . . Criminal intent by one [company] agent . . . may be imputed to the corporation, even though the criminal acts were committed by another. . . . Moreover, it is not necessary. . . to identify the actual agent who committed the crime if . . . [it] can [be] shown that some person within the corporation must have done so."

[12] *See, e.g.*, Julie R. O'Sullivan, *Some Thoughts on Proposed Revisions to the Organizational Guidelines*, 1 OHIO STATE J. CRIM. L. 487, 488–489 (2004) ("The "carrot and stick" approach grew out of the Commission's acceptance of three propositions. First . . . the Commission recognized that the respondeat superior principles of organizational liability did not adequately respond to gradations in corporate culpability . . . . Second, the Commission . . . believe[d] that corporations could 'hold out the promise of fewer violations . . . and greater detection and remediation of offenses when they occur through internal discipline, reformation of standard operating procedures, auditing standards, the corporate culture, and institution of corporate compliance programs reflecting such reforms.' Finally . . . the Commission concluded that it could create incentives for responsible corporate actors to foster crime control by the creation of a mandatory guidelines penalty structure that rewarded responsible corporate behavior and ensured certain and harsh sanctions for truly culpable corporations. In short, the Commission defined its objectives as: creating a model for the good corporate citizen; using the model to make corporate sentencing fair and predictable; and ultimately employing the model to create incentives for corporations to take crime controlling steps)." (Internal notes omitted).

[13] The Organizational Guidelines enumerate seven broad criteria for an "effective compliance program" and identify seven relevant factors for achieving this goal: (1) compliance standards and procedures reasonably capable of reducing the prospect of criminal conduct; (2) oversight by high-level personnel; (3) due care in delegating substantial discretionary authority; (4) effective communication to employees; (5) reasonable steps to achieve compliance that include monitoring and auditing systems as well as a system for reporting suspected wrongdoing without fear of reprisal; (6) consistent enforcement of compliance standards, including disciplinary mechanisms; and (7) upon detection of a violation, reasonable steps to respond and prevent further similar offenses. *U.S. Sentencing Commission, Report to the Congress: Increased Penalties under The Sarbanes-Oxley Act of 2002* (January 2003), 11–12, citing to U.S.S.G. §8A1.2, cmt. n.3 (k)(1–7).

[14] *See* United States Sentencing Guidelines Manual ("U.S.S.G.") § 8A1.2 Commentary (2001). *See also* Clark, *Foundations of White Collar Law and Practice*, at 24 ("In general, the Organizational Guidelines attempt to balance the seriousness of the offense with the manner in which the organization responded to this and to similar offenses . . . [by] determin[ing] the seriousness of the offense and the culpability of the organization through two factors, a base fine and a multiplier. The base fine is the greatest of the money gained by the organization from the crime, the amount of monetary loss caused by the offense (to the extent it was caused knowingly, intentionally or recklessly), or a pre-fixed amount. The culpability multiplier can either reduce the base fine by 95% or increase it by 400%. A resultant score is then translated and expressed in ranges on a table. Among the aggravating factors are organizations whose senior personnel willfully participated in or who tolerated criminally activities. Another aggravating factor, naturally, is a prior criminal history by the entity. Among the mitigating factors, as noted previously, are the self-reporting of violations, cooperation with authorities and having an effective program in place to prevent and detect violations of law").

[15] Among the most important of these policies are the Securities and Exchange Commission's widely read "Seaboard 21(a) Report" issued in 2001 [*available at* www.sec.gov/litigation/investreport/34-44969.htm <Site last visited on April 11, 2002>] in which the Commission outlined its requirements about

the quality and degree of cooperation by publicly traded entities worthy of some reward; the "Provider Self-Disclosure Protocol" developed by the Office of the Inspector General for the U.S. Department of Health and Human Services published at 63 FED. REG. 58399 *et seq.* (Oct. 30, 1998) [*available at* http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf <Site last visited on April 11, 2005>]; and, the corporate prosecutorial guidelines that the U.S. Department of Justice ("DOJ") announced in 1999 by then Deputy Attorney General Eric Holder (*Guidance on Prosecutions of Corporations*) and modified in 2003 under then Deputy Attorney General Larry Thompson which focus heavily on the extent and timeliness of a company's cooperation as a factor to be weighed in whether to indict a company.

[16] Green, *The Untimely Death (and Rebirth) of the Federal Sentencing Guidelines*, GEORGETOWN L.J. at 7. (Internal notes omitted).

[17] *See id*. ("The statutory maximum was constitutionally important . . . because it defined what punishment the jury had authorized through its guilty verdict. Jury verdicts in the federal system do not explicitly state the sentence or sentencing range to be imposed; on the contrary, juries are kept entirely ignorant of their verdict's consequences. Thus, the maximum sentence authorized by a jury's verdict is a matter of deduction . . . [based on] the statutory definition of the crime."

[18] U.S. CONST AMEND. VI provides:
In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses against him; to have compulsory process for obtaining witnesses in his favor, and to have the Assistance of Counsel for his defence.

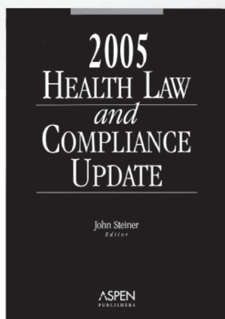
[19] *See* Paul F. Kirgis, *The Right to a Jury Decision on Sentencing Facts after Booker: What the Seventh Amendment Can Teach the Sixth*, GEORGIA L. REV., Vol. 39 (2005), at 1–3; [*available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=666942#PaperDownload] ("The Supreme Court allowed—indeed, encouraged—this process. The Court understood the Sixth Amendment's right to a jury trial in criminal cases simply not to apply at sentencing. The Court embraced a distinction between the "elements" of an offense and mere '"sentencing factors", requiring a jury determination on any matter labeled an"element", but not . . . for . . . "sentencing factors". And it gave legislatures almost total deference to define the "elements" of an offense . . . thus . . . transfer[ring] fact-finding authority to the judge." <Site last visited on April 12, 2005.>

[20] 530 U.S. 466, 120 S.Ct. 2348 (2000).

[21] Kirgis, *The Right to a Jury Decision on Sentencing Facts after Booker: What the Seventh Amendment Can Teach the Sixth*, GEORGIA L. REV., Vol. 39 (2005), at 3..[2]

2005 Health Law and Compliance Update

by John E. Steiner, Jr., Esq.



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