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Implications of the Sarbanes-Oxley Act for nonprofit entities

by Daniel Rinke, Contributing Editor

Nonprofit corporate governance practitioners gathered at a recent D.C. Bar luncheon to discuss the impact of the Sarbanes-Oxley Act of 2002 (SOX) (Pub.Law 107-204) on nonprofit entities. Largely a reaction to the recent round of Enron-esque scandals that rocked the financial world in 2001-2002, SOX was created to provide barriers to many of the corporate and accounting malfeasance issues that left shareholders and retirement accounts decimated. Practitioners are now exploring the scope and application of SOX, realizing that its reach extends far into the nonprofit sector.

Areas impacted by SOX. According to James Joseph, partner in the Washington, D.C., office of Arnold and Porter, the implications of SOX for nonprofit entities fall into five broad categories:

1. improved board oversight;
2. greater auditor independence;
3. enhanced internal systems for handling misdeeds;
4. new financial transparency measures; and
5. self-dealing restrictions and reporting.

Board oversight. In the board oversight realm, most SOX issues concern the independence of an audit committee of the board and improved reporting processes. Joseph noted that all audit committee members must be independent and the committee must disclose that no board member is a "credentialed financial expert."In addition, processes need to be in place to allow for the receipt and examination of reports concerning problems found by attorneys and employees regarding accounting issues.

Auditor independence. The primary issues concerning the independence of auditors and financial consultants involve services that might, in some way, jeopardize that party's independent judgment. To curb the risk to independence, apparently inherent in the auditing process, Joseph noted that SOX provides that auditors should be selected and monitored by the independent auditing committee and that the auditors make periodic reports to the committee. Joseph noted that questions still remain unresolved concerning the extent to which an auditor may perform additional services to the company, but observed that providing tax advice and preparing returns appear to be areas in which an auditor's independence is not jeopardized.

Internal systems. One of the more notable ways in which SOX enhances a company's internal systems is the requirement that the CEO and CFO certify the annual and quarterly reports. According to Joseph, "this poses an interesting dilemma for most CEOs because these individuals typically lack a financial or

Letters to the Editor

The CCH Healthcare Compliance team welcomes comments or questions regarding articles published in the CCH Healthcare Compliance Letter. Send comments to Raio G. Krishnayya, Coordinating Editor, at krishnar@cch.com. For more information about the CCH Healthcare Compliance Portfolio visit our online store at http://health.cch.com.

accounting background and may need to seek additional education before certification."

Nonprofit issues. With the foregoing in mind, Joseph outlined issues that nonprofit organizations should be considering in light of SOX. He said that "the first category a nonprofit should consider is making apparent the policies and procedures that the entity currently observes that are good practice under Sarbanes-Oxley."Joseph recommended providing formal written documents that outline an audit committee and its policies and powers, capping executive compensation (with attention to existing tax law) and formalizing prohibitions of lending transactions to officers and board members and conflict-of-interest provisions.

Joseph also suggested several novel ideas nonprofits should consider, including establishing a formal audit function supervised by the audit committee, certification of financial statements, adopting charters for key committees, improving internal audit processes, and encouraging greater monitoring and self-evaluation procedures, with particular emphasis on threats to board and auditor independence. ■

CCH Washington Bureau, June 5, 2003

Tax

HMOs required to provide more community benefits

by Catherine Hubbard, Contributing Editor

Tax-exempt HMOs will have a difficult time justifying their exempt status, unless they can illustrate that they provide a larger benefit to their communities, according to Don R. Spellmann, senior counsel at the Internal Revenue Service's Office of Chief Counsel, TEGE. Commenting on the U.S. Court of Appeals for the Tenth Circuit's recent *Intermountain Health Care* (IHC) HMO cases and the U.S. Court of Appeals for the Third Circuit's *Geisinger* case during a recent conference call, Spellmann said the cases increase the need for more community involvement. "These cases tell you that an HMO—that is an arranger type of HMO—will have a tougher road to hoe to qualify for exemption either under 501(C)(3) or (C)4," he said during the call, which was sponsored by the American Bar Association.

According to Spellmann, it was difficult for IHC Care and IHC Group to qualify because they were arranging services for large employer groups. "When all your doing is arranging for large employers it's difficult to argue that some larger community benefit is being served."

Moreover, IHC didn't explain adequately the method by which it set different premiums for large employers and small employers, leading to the question that large employers were being preferentially treated, Spellman said. If IHC Health Plans had more favorable facts, such as a community outreach program, or free membership to even a small number of low-income people, it is possible the case would have had a different result, he added. "The question is what are you doing for the general public."

In *IHC Health Plans Inc. v. Commissioner*, 2003 TNT 70-6 the Tenth Circuit upheld the denial by both the Tax Court and the IRS of section 501(c)(3) status for three HMOs. The Tenth Circuit concluded that "a health-care provider must make its services available to all in the community plus provide additional community or public benefits."

Frederick J. Gerhart, with Dechert LLP, Philadelphia, Penn., said the Tenth Circuit is following Rev. Rules 69-545 and 83-157, when it held that HMOs need to do something in addition to providing health care for members only. But Douglas M. Mancino, with McDermott Will & Emery, Los Angeles, California., said the Tenth Circuit "carefully ignored" IRS Rev. Rul. 69-545 and instead opted for a "more restrictive, more proscriptive test," requiring a community benefit beyond standard fee-for-service health care. "This raises questions for startup organizations that do not have the ability to do the plus things," he said, noting that many HMOs will not have adequate resources.

A copy of the materials can be found at: http://www.abanet.org/cle/programs/nosearch/materials/t03hbbcm2.pdf and athttp://www.abanet.org/cle/programs/nosearch/materials/t03hbbcm1.pdf. ■

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More HealthSouth execs plead guilty to fraud

by Sharon Sofinski

Three more HealthSouth executives have agreed to plead guilty to fraud charges, the U.S. Attorney's Office for the Northern District of Alabama has announced. The charges stem from the ongoing investigation into HealthSouth's accounting activities, conducted by the U.S. Attorney's Office, the Internal Revenue Service, the FBI, and other agencies.

Jason Brown, Richard Botts, and Will Hicks are the twelfth, thirteenth, and fourteenth individuals to be charged in the investigation, which began in March 2003.

Charges. Brown, HealthSouth's vice president of finance, has agreed to plead guilty to conspiracy to commit securities fraud, falsifying books and records, and wire fraud. Brown allegedly conspired to inflate HealthSouth's reported earnings and assets by falsifying entries in its books and its filing reports with the SEC and other agencies. He is also charged with giving a false stock sale document to HealthSouth's treasury department and accounting staff, who in turn presented it to the company's auditors. He faces a maximum penalty of five years in prison and a $250,000 fine.

Botts, HealthSouth's senior vice president for tax, has agreed to plead guilty to conspiring to commit securities fraud, falsifying books, and mail fraud. Botts and others allegedly gave false tax information to state tax authorities and the IRS to help conceal bogus assets and the scheme to inflate earnings. He is also charged with submitting, through the mail, tax returns that contained false information. Botts could face a maximum five-year prison sentence and a fine of up to $250,000.

Hicks, vice president of investments for HealthSouth, has agreed to plead guilty to conspiracy to make false statements to auditors and maintain false books and records. According to the government, Hicks and other employees gave false statements to auditors and omitted facts in connection with an audit of HealthSouth's 2000 and 2001 financial statements. He also faces a maximum sentence of five years and a $250,000 fine.

> **"This is not mere 'accounting fraud,' but rather a business scheme to fraudulently boost HealthSouth's reported earnings."**

Revenue, earnings inflated. As a result of these fraudulent schemes, HealthSouth's revenue and earnings were inflated by hundreds of millions of dollars on publicly filed reports. According to U.S. Attorney Alice Martin, "This is not mere 'accounting fraud,' but rather a business scheme to fraudulently boost HealthSouth's reported earnings."

Brown, Botts, and Hicks have agreed to cooperate with the government's continuing investigation into HealthSouth's finances. Their hearings will be scheduled at a later date.

Investigation ongoing. The investigation into HealthSouth's activities continues." We will continue to widen the net of our investigation to reach all those individuals who participated in this fraud," Martin said. The recent charges bring the number of HealthSouth executives charged in the fraud investigation to fourteen. Among those charged earlier this year were former HealthSouth CFOs Aaron Beam, Michael Martin, William Owens, and Weston Smith; treasurer Malcolm McVay; and vice president of finance Emery Harris. All are cooperating with the investigation.

HealthSouth, based in Birmingham, Alabama, is the country's largest provider of outpatient surgery, diagnostic imaging, and rehabilitative health care services, with approximately 1,700 locations in the United States and abroad. Copies of the DOJ press releases regarding the HealthSourth investigation can be found at DOJ Press Release #401, July 8, 2003; DOJ PressRelease #436, July 31, 2003. ■

CCH Chicago Bureau, July 2003

Compliance issues related to the protection and safety of human participants in medical research studies

by Patricia Brent, J.D., M.P.H.

The importance of compliance in the provision of clinical research services is a" hot button" issue these days. Watchdogs from the federal government have placed clinical research studies directly under their powerful microscope. Regulatory violations associated with the provision of clinical research services may be divided into three broad areas:

- *claims submission, reimbursement and other associated compliance concerns, such as violations of the Antikickback statute;*
- *concerns related to protecting the rights and safety of participants in clinical research studies; and*
- *concerns that are focused on the relationship between the researcher and the funding source or research sponsor.*

Compliance issues relating to claims submission, reimbursement and antikickback violations were addressed in the June 9, 2003 CCH Healthcare Compliance Letter.[1] This article explores compliance issues associated with the protection of the rights and safety of clinical research participants.

Historical Perspectives

Experts frequently define compliance as, simply," doing the right thing." If compliance is" doing the right thing" when submitting a claim, coding a patient encounter, or documenting services in a patient's chart, then "doing the right thing" certainly extends to direct patient care services, since the patient *is* the primary focus and beneficiary of healthcare services. The provision of any clinical service, whether for the purpose of diagnosis and treatment alone or in conjunction with clinical research, is guided by long-standing, well-established ethical principles, i.e.: "doing the right thing."

One outcome of the Nuremberg war crimes tribunals was the publication of a code of ethics setting forth ten principles regarding the moral responsibility for human medical experimentation.[2] The Declaration of Helsinki followed in 1964, outlining additional ethical considerations for protecting human participants in medical research.[3]

In 1974, Congress passed the first federal law protecting the rights and safety of human participants in clinical research studies and requiring those who receive federal funding for this research to comply with specific federal regulations, known as the National Research Act.[4] The Act also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was charged with identifying the basic ethical principles involving medical research conducted on human participants. Subsequently, these principles were identified in the Belmont Report.[5]

Ethical Principles

The Belmont Report outlines three guiding principles for the ethical conduct of clinical research:[6]

1. respect for persons;
2. beneficence; and
3. justice

Any decision to include human participants in a medical research study must consider these three principles as the basis for proceeding.

The duty to respect people demands that a person's (or, in the case of medical care, a patient's) right of autonomy (or self-determination) be protected. Autonomy is defined as (1) the right of a patient to make choices regarding the type and the extent of medical treatment, and (2) the duty to protect individuals with reduced autonomy, such as children or incompetent adults.[7] It also demands that human participants enter medical research studies voluntarily and with adequate information.

In the case of research, beneficence means that researchers and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that may occur to a participant in a medical research project.[8] Finally, justice is defined, in clinical research terms, as the right to fair and equitable treatment in the selection of research participants, so that vulnerable groups of individuals (such as minorities and the poor) are not overly exposed to the risks of medical research.[9]

Specific Protections

In 1981, the government formalized these three principles into the "Federal Policy for the Protection of Human Subjects," generally known as the "Common Rule. "[10] Subsequently, the government codified the core of the" Common Rule" into a uniform set of regulations that governs human subject research conducted by 17 federal agencies, the Central Intelligence Agency (CIA) and all federally funded research, as well as private funding for research with drugs or medical devices that are regulated under FDA rules. They are found, primarily, in the following:

- **45 CFR 46** – DHHS' Office of Human Research Protection (OHRP) - Protection of Human Subjects Involved in Medical Research Projects Receiving Federal Funds; and
- **21 CFR 50** – Food and Drug Administration (FDA) - Human Subjects Protections. [11]

Specifically, the mandate three basic protections for human participants in medical research:

- Informed consent;
- Institutional Review Board (IRB) review; and
- Institutional assurances.

In addition to the ethical principles that are codified in the Common Rule, the recently enacted HIPAA Privacy Rule affords additional protections of privacy for clinical research participants.[12] For compliance officers and other health care managers charged with the responsibility for assuring compliance in clinical research, compliance activities should be focused on these basic protections. This article highlights the issues associated with informed consent and institutional review boards. Institutional assurances and the HIPAA Privacy Rule will be discussed in the final article in this series.

Informed Consent

A prominent feature of the Common Rule is the informed consent requirement, a cornerstone of modern research ethics. Informed consent is both an ethical duty and a legal standard. As an ethical duty, it is grounded in the principle of autonomy and self-determination, reflecting respect for the participant's capacity for choice.[13] As a legal standard, its origins are in the intentional tort of battery, the common law that sanctions unauthorized, offensive touching.[14]

Informed consent suggests that any consent given is legitimate only after adequate information is provided that allows an individual to make an "informed" choice. Before an individual can make an" informed" decision, the information that is required that is the basis for the decision must be presented in language that is understandable, especially important in clinical research studies.[15] Moreover, consent must be sought under circumstances that minimize the possibility of coercion or undue influence.[16]

Although viewed more as a process rather than as a single event with its resultant signed form, to be "informed," the consent (for clinical research) must contain the eight basic information elements outlined in the Common Rule, including the following:[17]

- a statement that the study involves research, an explanation of the purposes of the research, and a description of the procedures to be followed;
- a description of any reasonably foreseeable risks or discomforts to the participant;
- a description of any benefits to the participant or to others that might reasonably be expected;
- a disclosure of alternative procedures or courses of treatment;
- a statement describing the extent to which confidentiality of records identifying the subject will be maintained;
- for research involving more than a minimal risk, an explanation of the availability and nature of any compensation or medical treatment if injury occurs;
- identification of whom to contact for further information about the research and about subjects' rights, and whom to contact in the event of a research-related injury; and
- a statement that participation is voluntary, that refusal to participate in the research study will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may continue to participate at any time.

The consent form itself must be approved by the instutional review board (IRB), the written form documented and signed by the participant or the participant's authorized representative and filed with the IRB.[18]

In addition to the above elements, the Common Rule includes several additional elements of consent that are applicable in special circumstances, such as research involving children[19] or research involving prisoners.[20]

The law imposes an affirmative duty on physicians and medical researchers to adequately inform patients or clinical research participants. Failure to obtain informed consent prior to treatment may be considered as a legal cause of action against the physician or medical researcher for negligence since, allegedly, they have breached their professional duty to provide adequate information to their patient.

Compliance Tips: Informed Consent

Effective compliance actions that focus on the informed consent process should include the following:

- reviewing consent forms on a regular basis to ensure the information contained within is still valid and that the form is written in an understandable manner;
- interviewing a random sample of research participants to assess if the consent process is providing them with adequate

and understandable information and if they have had appropriate opportunities to ask questions and receive answers from the researchers;
- providing oversight by carefully monitoring the consent process when the participant is a member of a vulnerable population group, such as a child, a non-competent adult, or an aged or infirm person; and
- assuring, when you are designing your consent form and process, that it conform to the laws in your own state.

Institutional Review Boards

IRBs play an important role in the efforts to protect human participants involved in clinical research studies. Federal regulations mandate that an IRB review and approve of all research involving human participants.[21] An IRB is defined as any board or committee "formally designated by an institution to review, to approve the initiation of, and to conduct periodic reviews of biomedical research involving human subjects."[22] It has the authority to approve, require modifications in, or disapprove of a proposed clinical research study.[23] IRBs also have the authority to suspend the research study if it is found to entail unexpected or undue risks to participants or if research does not conform to the Common Rule or institution's additional protections.[24] IRB approval of a project, in part, means that:[25]
- procedures are used that are consistent with sound research design and do not expose the participant to excess risk, thereby minimizing the risk of participation;
- anticipated risks to humans are reasonable in relation to anticipated benefits;
- selection of participants is equitable; and
- prior informed consent from each participant will be sought and appropriately documented.

IRBs are responsible for reviewing the research protocols and the scientific aspects of all clinical research studies, including all supporting information, and judging the adequacy of the informed consent document, prior to determining if the research study may proceed.[26] IRBs also must demonstrate that they meet the standards set out in the federal regulations, keep minutes of all their meetings and issue the approval or denial letters for all requests for research projects.[27] IRBs are inspected, reviewed and monitored by the federal government to ensure that they are acting in compliance with the regulations.

An IRB must be composed of no less than five experts and laypersons of varying backgrounds, including researchers, clinicians, and representatives of the local community, to ensure a complete and adequate review of proposed clinical trial activities.[28] In addition to possessing the professional competence needed to review specific activities, regulations require that IRBs be knowledgeable about the local research context, including:[29]
- the IRB must be sufficiently qualified through experience, expertise and diversity of its members, including race, gender, cultural background and sensitivity to such issues as community attitudes to promote respect for its advice and counsel; and
- the IRB must be able to evaluate research in terms of institutional commitment, applicable law and standards of professional conduct and practice.

Usually, an IRB is created by a hospital or academic medical center to be part of its organizational structure. But some IRBs are freestanding, i.e., they are not associated with any particular hospital or academic medical center.

HHS regulations require that an institution have written IRB procedures for each of the following:[30]
- for conducting its initial review of research;
- for conducting its continuing review of research;
- for reporting its findings and actions to investigators and the institution;
- for determining which projects will require review more often than annually;
- for determining which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review;
- for ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the participant; and
- for ensuring prompt reporting to the IRB, the appropriate institutional officials, any Department of Agency head, and the Office of Human Research Protection (OHRP) of any (1) unanticipated problems involving risks to participants or others, (2) any serious or continuing noncompliance with 45 CFR Part 46t or the requirements or determinations of the IRB, and (3) any suspension of termination of IRB approval.

The regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review and approval.[31] However, review of research activities *is* permitted through the IRB expedited review process when it is determined that the research activities (1) present no more than minimal risk to participants, and (2) involve only procedures listed in one or more categories listed in the regulations.[32]

Compliance Tips: IRBs

Recently, IRBs have come under heavy federal scrutiny as tragic outcomes in certain cases have highlighted their failings.[33] Compliance with federal IRB regulations is now a "front and center" subject for compliance officers and clinical researchers. A good place to start, when focusing on your IRB compliance program, is to consult the guidances published by the OHRP.[34] Other compliance actions, when taken, will help reduce the risk of regulatory violations. Recommended actions include:
- reviewing IRB written policies and procedures to assure that they are in accord

with recommended policies and procedures outlined in the Guidance;[35]

- developing specific training to adequately inform IRB members, as well as institutional leaders, regarding the obligations of the IRB and updating training on a regular basis;
- reviewing IRB operations structures and reporting mechanisms, including reviewing workloads, expertise of committee members, meeting attendance, documentation of training and review of decision-making processes;
- reviewing participant recruitment processes, including assuring fair and equitable recruitment procedures;
- reviewing reporting of adverse events; and
- consideration for appointing a specific individual who will be responsible for ensuring that regulatory requirements are met.

Summary

In summary, there are three protections that comprise the basis of federal regulations for participants in medical research: informed consent, IRBs and institutional assurances. These originate from deeply rooted ethical principles as well as legal standards. Effective research compliance programs should focus their activities on these three protections. ■

Patricia Brent, J.D., M.P.H., is president of Morgan Hill Associates, a consulting firm devoted to assisting small health care providers with regulatory compliance. She has several years' experience working in NIH-sponsored research programs and previously has held senior hospital administrative positions. She currently serves as a member of a hospital Medical Ethics Committee. She is also author of Understanding Reimbursement for Investigational Drugs and Devices, published by CCH Incorporated, April 2003. For more information or comments, please contact the author at 603-469-3536.

1 Patricia Brent, J.D., M.P.H., *Compliance Issues in Clinical Trials: Billing, Claims Submission, and Anti-kickback Concerns,* CCH Healthcare Compliance Letter, Vol. 6, Issue 11, June 9, 2003.

2 G. J. Annas and M.A. Grondin, eds., *The Nazi Doctors and The Nuremberg Code: Human Rights in Human Experimentation,* Oxford University Press, New York, 1992.

3 World Medical Association, *Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects* (Helsinki, Finland, 1964).

4 42 U.S.C. 201-300aaa-13.

5 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research,* Washington, D.C. U.S. Dept. of Health, Education & Welfare, 1978.

6 Id.

7 Allan Brett, M.D. and Michael Grondin, M.D., *Ethical Aspects of Human Experimentation in Health Services Research,* JAMA 265: 1854 – 1857, 1991.

8 Id.

9 Id.

10 45 CFR 46, Subpart A.

11 Id.

12 *Final Rule,* 67 FR 53181-53273, Aug. 14, 2002.

13 Faden, R.R. and Beauchamp, T.L.: *A History and Theory of Informed Consent,* Oxford University Press, New York, 1986.

14 *Canterbury v. Spence,* 464 F. 2d 772, 780 (D.C. Cir), cert. denied, 409 U.S. 1064 (1972). See also: *Natanson v. Kline,* 186 Kan. 393, 350 P. 2d 1093 (1960) and *Cobbs v. Grant,* 8 Cal. 3d 229, 502 P. 2d 1, 104 Cal. Rptr. 505(1972).

15 45 CFR 46.116.

16 45 CFR 46.116 (a)(8).

17 45 CFR 46.116(a)-(f).

18 45 CFR 46.117.

19 45 CFR 46, Subpart D.

20 45 CFR 46, Subpart C.

21 45 CFR 46.103(a).

22 45 CFR 46.102(g).

23 45 CFR 46.109(a)-(e).

24 45 CFR 46.113.

25 45 CFR 46.111.

26 Id.

27 45 CFR 46.115, 116.

28 45 CFR 46.107.

29 Id.

30 45 CFR 46.103(b)(4), (5).

31 45 CFR 46.103(b) and 45 CFR 46.116(f).

32 45 CFR 46.110(b)(1).

33 See Patricia Brent, J.D., M.P.H., *Compliance Issues in Clinical Trials: Billing, Claims Submission and Anti-kickback Concerns,* CCH Healthcare Compliance Letter, Vol. 6, Issue 11, June 9, 2003, endnote #1.

34 Guidances are published on the OHRP website: http://ohrp.osophs.dhhs.gov.

35 *Guidance on Written ORB Procedures,* Washington, D.C., Office of Human Research Protections (OHRP), Dept. of Health and Human Services, July 11, 2002.

Revised prosecution principles issued

by Geraldine S. Stroka, J.D., R.N., M.S.N.

Most corporate professionals these days believe that the Sarbanes-Oxley Act is the primary issue in corporate governance. Think again. The Corporate Fraud Task Force in the Department of Justice (DOJ) has issued its revised set of principles for federal prosecutors. These guidelines entitled, "Principles of Federal Prosecution of Business Organizations," are contained in a DOJ Memorandum to assist prosecutors in their decision whether to charge a business organization.

Corporation'sauthenticity. These revised principles are the direct result of the combined efforts of the Corporate Fraud Task Force and the Attorney General's Advisory Committee. Their main focus is the authenticity of a corporation's cooperation when under investigation by the DOJ. Under these revisions, any business organization's effort to impede a DOJ's investigation weighs heavily towards prosecution of that entity. In addition, these revisions require that an organization's compliance program be effective, not a mere "paper program."

General principle. The general principle underlying these revisions is that corporations, because of their artificial nature, should not be treated more leniently or more harshly. In addition, prosecutors need to know that indictment of a corporation may:

1. derive an important public benefit;
2. result in specific deterrence by initiating cultural change within that organization; and
3. serve a substantial federal interest because certain crimes that carry a substantial risk of public harm may be more likely to have been committed by businesses.

General factors. The same factors are utilized in prosecuting an individual as well as a corporation. These factors are (1) sufficiency of the evidence; (2) likelihood of success at trial; (3) the probable deterrent, rehabilitative, and other consequences of conviction; and (4) the adequacy of noncriminal approaches.

Specific factors. When a prosecutor is (1) conducting an investigation, (2) determining whether to bring charges, and (3) negotiating plea agreements, nine additional factors should be considered. These additional factors are the following:

1. the nature and seriousness of the offense;
2. the pervasiveness of the wrongdoing within the corporation;
3. the corporations's history of similar conduct;
4. the corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation including, if necessary, the waiver of corporate attorney-client and work product protection;
5. the existence and adequacy of the corporation's compliance program;
6. the corporation's remedial actions;
7. collateral consequences;
8. adequacy of the prosecution of responsible individuals; and
9. the adequacy of remedies such as civil or regulatory enforcement actions.

The general principle underlying these revisions is that corporations, because of their artificial ature, should not be treated more leniently or more harshly.

Importance. These principles have enormous implications for all forms of business organizations, including partnerships, sole proprietorships, government entities, and unincorporated associations.

One specific factor, an organization's voluntary disclosure and its cooperation, requires intensive review. Under these revised principles, prosecutors, when determining a corporation's cooperation, may consider the corporation's willingness to:

1. identify culprits within that organization;
2. make witnesses available;
3. disclose the complete results of its internal investigation; and
4. waive attorney-client and work product protection.

Waiving attorney-client privilege could have dire consequences, should civil litigation be filed. Any documents, tapes, etc., where the privilege has been waived, may be "discoverable" during the course of civil litigation. Also, despite a corporation's best efforts to cooperate, prosecution and economic policies specific to the industry or statute may require prosecution.

Federal prosecutors have been given the green light to vigorously prosecute business organizations. Compliance officers need to review their organizations and their compliance programs in light of these revised principles. Based on the experience with these revised principles, there may be future revisions. ■

U.S. Department of Justice Office of the Deputy Attorney General, Memorandum, Jan. 20,2003, ¶350,000

A Letter of Thanks

The Healthcare Compliance Team would like to wish Jeff Reinholtz, J.D.—the team's Portfolio Managing Editor—best wishes as he embarks on a new assignment, leading the CCH payroll and pension products. Jeff brought his 15 plus years of experience in the publishing world as well as his practical expertise as a practicing attorney to making CCH and the Healthcare Compliance products, a leader in this market. Under Jeff's leadership, this team has honed its customer-based skills and has not only maintained but increased its commitment to quality, content analysis. To Jeff, we say, thanks to a good friend and mentor. We wish you Godspeed and great success in your next leadership role.

Sincerely
The Healthcare Compliance Team