CCH Health Care Compliance Letter

Volume 8, Issue 2 health.cch.com January 24, 2005

On The Front Lines 4

Compliance program effectiveness: Key issues by Louis H. Feuerstein and Deborah Joslyn

Fraud and Abuse 1

- OIG enters into CIA, settlement agreement with HealthSouth
- OIG approves proposed arrangement to subsidize malpractice insurance costs
- Charitable foundation not sanctioned for donations made within hospital system

HIPAA 3

- CMS to announce specifics on applying for NPIs in the spring

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.

OIG enters into CIA, settlement agreement with HealthSouth

by Gené Stephens Connolly, JD, Contributing Editor

The Office of Inspector General (OIG) entered into a Corporate Integrity Agreement (CIA) with HealthSouth Corporation, a provider of inpatient and outpatient rehabilitation services, as well as a separate settlement agreement. The five-year CIA requires HealthSouth to establish and maintain a compliance program within ninety (90) days of the January 1, 2005 effective date of the agreement that addresses:

(1) federal health care program requirements regarding physician certification or recertification of outpatient therapy plans of care for Medicare beneficiaries receiving care in outpatient departments of HealthSouth's rehabilitation hospitals;

(2) the proper use of group and individual therapy codes for rehabilitation services furnished to Medicare beneficiaries in outpatient rehabilitation facilities or outpatient departments of HealthSouth's rehabilitation hospitals;

(3) compliance with Medicare coding rules applicable to outpatient therapy services including, but not limited to, rules for time therapy services;

(4) the use of licensed personnel to furnish services to federal health care program beneficiaries; and

(5) the preparation and filing of Medicare and Medicaid cost reports for HealthSouth rehabilitation hospitals and the accurate calculation of any separate program payments to such facilities, including payments for outlier claims, bad debt, indirect medical education, and low income patients.

The settlement agreement further requires HealthSouth to engage an independent review organization to perform an audit and evaluation of the Corporation's billing, coding and cost reporting practices with respect to its inpatient and outpatient rehabilitation services. Additionally, HealthSouth must maintain a disclosure program that includes a mechanism for a toll-free compliance telephone line to enable individuals to disclose to the Corporation's Compliance Officer, or some other person who is not in the disclosing individual's chain of command, any identified issues or concerns associated with HealthSouth's policies, conduct, practices, or procedures. ■

OIG Corporate Integrity Agreement, January 1, 2005, ¶420,097

OIG approves proposed arrangement to subsidize malpractice insurance costs

by Gené Stephens Connolly, JD, Contributing Editor

The OIG determined that a hospital's proposed arrangement to subsidize the cost of tail coverage and increased medical malpractice premiums for two neurosurgeons would not generate prohibited remuneration under the Anti-Kickback Statute.

Under the arrangement, the hospital offered to provide "Premium Support" to the physicians by subsidizing: (1) the entire cost of tail coverage from the physicians' original insurance carrier; (2) a portion of the increased premiums for claims-made coverage from the physicians' new carrier; and (3) all or part of the costs of tail coverage from the physicians' new carrier. The physicians would, however, continue to incur out-of-pocket expenses for their malpractice insurance and would only receive Premium Support in the second year of their service to the hospital if the community need for neurosurgery persisted or if the physicians faced significant premium increases. The hospital further certified that: (1) the amount of Premium Support would not take into account the volume or value of referral business generated by the physicians for the hospital; (2) the physicians were not required to refer patients; and (3) the physicians could furnish services at sites other than the hospital, which also would be covered by the subsidized malpractice insurance.

The OIG determined that the circumstances of the hospital's Premium Support arrangement adequately reduced the risk of improper payments for referrals because the arrangement was implemented as a temporary and urgent measure to prevent a gap in the availability of neurosurgical services in the community. In addition, the arrangement was structured to prevent a significant financial windfall to the physicians, as each physician would continue to incur annual out-of-pocket expenses. Premium payments also would be paid directly to the insurer. The hospital's risk of violating the Anti-Kickback Statute was further minimized because the agreement would not require that the physicians refer patients to the hospital. Finally, the hospital's arrangement provided flexibility to the physicians to furnish services at other medical sites.

OIG Advisory Opinion No. 04-19, ¶500,122 ■

Charitable foundation not sanctioned for donations made within hospital system

by Anuradha Gupta, JD, Contributing Editor

A charitable foundation will not be subject to fines under section 1128B(b) of the Social Security Act, which prohibits knowingly and willfully offering to pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program, for donations the foundation made to a hospice within the same health system. Despite the nonprofit, bonafide charitable pupose served by the donations, the foundation's donations here warrant closer scrutiny because of the donor-foundation's affiliation with the health system through its common officers and directors and the potential federal health care business that the hospice may generate for the health system.

Fraud or abuse unlikely. Under its proposed donation plan, the foundation would make unrestricted donations up to a certain amount per year over a consecutive five-year period to the hospice care center. The foundation certified that neither the offer nor the amount of the proposed donations will be determined in a manner that varies with, or otherwise takes into account in any way, the volume or value of any referrals or other business that the hospice might generate. Additionally, the hospice may, but is not required to, purchase items or services from the health system. The Office of the Inspector General (OIG) determined that the proposed donations are unlikely to result in fraud or abuse under the anti-kickback statute because (1) it is unlikely that any purpose of the proposed donations would be to generate business for the health system, (2) the proposed donations will be unrestricted as to the use of the funds, and neither the foundation nor the health system will exert any influence over the hospice's use of the funds, and (3) the proposed donations will be subject to an annual cap and a fixed duration.

Potential anti-kickback violation. Donations to the hospice will be used to establish an inpatient hospice that accepts patients without regard to their ability to pay, increasing the availability of inpatient hospice services in

Managing Editor
Pamela K. Carron, J.D.

Coordinating Editors
Angela Fanelli, J.D.
Sharon Sofinski

CCH Washington Bureau
Paula Cruickshank
DOJ, FTC–John Scorza
SEC–Peter Feltman
Health Law–Catherine Hubbard
Tax–Jeff Carlson, David Hansen

Designer
Laila Gaidulis

Comments from readers are welcome and should be directed to Sharon Sofinski at SOFINSKS@CCH.COM, Tel. 847-267-7860, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

CCH Health Care Compliance Letter is published 24 times a year by CCH INCORPORATED, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A. All rights reserved. ©2005 CCH INCORPORATED, A WoltersKluwer Company.

No claim is made to original government works; however, the gathering, compilation, and arrangement of such materials, the historical, statutory and other notes and references, as well as commentary and materials in this Product or Publication are subject to CCH's copyright.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting or other professional service. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

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

the region and furthering the foundation's mission. If the foundation's intent was to induce or reward referrals of federal health care program business to the health system, the proposed donations could generate prohibited remuneration under the anti-kickback statute. In this case, however, the inducement or rewarding of referrals is not present here and therefore, no sanctions were imposed. ■

OIG Advisory Opinion 04-18, ¶500,121

HIPAA

CMS to announce specifics on applying for NPIs in the spring

by Catherine Hubbard, MA, Contributing Editor

Health care providers should start preparing to apply for and use National Provider Identifier numbers (NPIs), according to the Centers for Medicare & Medicaid Services (CMS). "We expect health plans to prepare for the NPI," said Helen Dietrick of the Program Integrity Group in the Office of Financial Management at CMS. Health plans, including Medicare and Medicaid, are responsible for incorporating the NPI in standard transactions, she said during a CMS conference call in December.

The agency plans to announce specifics of the registration process in the spring of 2005, said Dietrick. She noted there will be three ways to apply for an NPI: on paper, through the Web and through an electronic file interchange. However, CMS hopes to receive most applications through an interactive web application, she said.

Dietrick said the electronic file interchange, expected to be available late 2005, will allow organizations, such as health plans or a group practice with whom they do business, to apply on their behalf in a mass enumeration effort.

In January 2004, CMS published the final rules for the NPI. Health care providers may begin applying for the numbers on May 23, but they will have two years before they must comply with the rule, or three if they are small health plans.

The NPI will be used in HIPAA standard transactions by covered entities such as health plans, health care clearinghouses and providers who transmit any health information in electronic form, according to Pat Peyton with the Office of HIPAA Standards at CMS.

All covered providers must obtain and use NPIs in standard transactions, said Peyton. The purpose of the NPI, she said, is to "uniquely identify every health care provider so that they can be identified in standard transactions."

The NPI final rule requires a covered organization to obtain a number for itself and for any subpart of itself that would be covered if it were a separate legal entity, Peyton explained. For instance, she said, a dialysis unit within a hospital that submits standard claims to health plans is not a legal entity, but is a subpart. In that case, the hospital "must ensure that the dialysis unit obtains an NPI," she said. She clarified that all covered entities under HIPAA are legal entities, but noted that the subpart concept does not apply to individuals. "An individual person could never be a subpart," she said in response to a provider's question.

Peyton observed, however, that all providers, as defined in the HIPAA regulations, are eligible for NPIs, regardless of whether they are HIPAA covered entities. "We encourage non-covered health care providers to apply for NPIs and to comply with the requirements that the NPI final rule places on covered healthcare providers," she said.

Transitioning to NPIs for Medicare. Eventually, NPIs will replace the Medicare billing numbers used by Medicare providers. "NPIs will one day be the billing numbers," said Peyton. She added that providers eligible to enroll in Medicare must have Medicare billing numbers. They should obtain NPIs and make sure all subparts obtain NPIs as well, she said.

"The NPI final rule wants to make sure that covered organization healthcare providers ensure that any parts within them comply with other federal regulations which would be the federal regulations that Medicare uses when they enroll providers," said Peyton.

NPI database. Eventually the NPIs are going to be included in a national database, said the speakers. CMS hopes to issue a Federal Register notice about its data dissemination policy by May, with the hopes of getting a system up and running in late 2005, they said.

For more information, email CMS at askhipaa@cms.hhs.gov or call 1-866-282-0659. ■

CCH Washington Bureau, January 17, 2005

CCH Health Care Compliance Editorial Advisory Board

Timothy P. Blanchard, Esq.
McDermott, Will & Emery

Patricia L. Brent, J.D., M.P.H.
President, Morgan Hill Associates

Neil B. Caesar, Esq.
President
The Health Law Center

Paris Cavic, Esq.
Albany, New York

Bill Dacey, MBA, MHA, CPC
President, The Dacey Group

Paul R. DeMuro, J.D., MBA
Partner
Latham & Watkins

Louis H. Feuerstein
Corporate Compliance Program National Leader
Ernst & Young

Cynthia Reaves, Esq.
Honigman Miller Schwartz and Cohn

William P. Schurgin, Esq.
Seyfarth, Shaw, Fairweather & Geraldson

John E. Steiner, Jr., Esq.
Chief Compliance Officer for
Cleveland Clinic Health System

Sanford V. Teplitzky, Esq.
Ober, Kaler, Grimes & Shriver

On The Front Lines

Compliance program effectiveness: Key issues

by Louis H. Feuerstein and Deborah Joslyn

This article is an excerpt from the "Compliance Program Effectiveness" chapter in the 2005 Health Law and Compliance Update, edited by John Steiner, Jr. For more information or to order the book, call Aspen Publishers at 1-800-638-8437 or visit www.aspenpublishers.com.

Based on the OIG's compliance program guidances (CPGs) and the Federal Sentencing Guidelines, any review and assessment of compliance program effectiveness starts with an evaluation of the seven elements of the program and how they are working.

Some effectiveness issues lend themselves to quantitative measurement with comparative ease. Examples include compliance training and screening for a health care organization's employment of or dealing with sanctioned or excluded individuals. With most effectiveness measures, there can be no such thing as perfection. A health care organization could train with great focus and diligence—and spend significant sums in the process—and still end up with an ill-informed or rogue employee committing acts that result in significant compliance exposure for the organization. Similarly, a sufficiently clever and motivated individual perhaps could beat even the most comprehensive compliance controls. The goal with the effectiveness issues discussed below is not perfection. Rather, the goal is to take a cost-effective course of action to establish reasonable safeguards and, importantly, to document that the health care organization has worked diligently to achieve an effective program.

Compliance Program Oversight

Oversight of a compliance program should include those individuals who have both the responsibility and authority to address compliance issues. It is also important that these individuals have the appropriate subject matter expertise and general management background, so that they can provide recommendations for the ongoing effectiveness of the program. Oversight should begin with a compliance officer and continue with a compliance management committee including key representatives from all of the major risk areas of the organization. Finally, the organization should provide oversight by a board of directors committee whose responsibility includes the evaluation of the strategic direction and ongoing effectiveness of the compliance program.

Board Oversight

While the CPG, Corporate Integrity Agreements (CIAs), and OIG-American Health Lawyers Association (AHLA) board resources are silent in terms of composition of the board of directors compliance committee, a health care organization would want, at minimum, to ensure that each voting committee member is an independent director, is qualified to ask questions regarding the compliance program, and has received training regarding his or her compliance oversight responsibilities. Moreover, given the increasing focus on compliance program effectiveness, organizations should re-examine the amount of time that is given to discussing the compliance program's operation, including how often the committee meets.

A Board compliance committee member's obligations include a fiduciary duty to ensure that the compliance program is meeting the needs of the organization. Failure to do so under some circumstances may, in theory at least, render a director liable for losses caused by noncompliance with applicable legal standards. Clearly, a health care organization may be at risk, and directors, under extreme circumstances, also may be at risk, if they fail to reasonably oversee the organization's compliance program or act as mere passive recipients of information. On the other hand, courts traditionally have been loath to second-guess boards of directors that have followed a careful and thoughtful process in their deliberations, even where ultimate outcomes for the organization have been negative. Similarly, courts have consistently upheld the distinction between the duties of boards of directors and the duties of management. The responsibility of directors is to provide oversight, not manage day-to-day affairs. It is the process the board follows in establishing that it had access to sufficient information and that it has asked appropriate questions that is most critical to meeting its duty of care.

The board should fully understand and approve management's process for evaluating and responding to violations of the health care organization's policies and procedures, as well as applicable federal and state laws and regulations. In addition, the board should receive sufficient information to evaluate the appropriateness of the organization's response to detected compliance issues.

Suggested questions for the board to consider include:

- How is the compliance program structured, and who are the key employees responsible for its implementation and operation? How is the board structured to oversee compliance issues?
- What are the goals of the organization's compliance program? What are the inherent limitations in the compliance program? How does the organization address these limitations?

- Does the compliance program address the significant risks of the organization? How were those risks determined, and how are new compliance risks identified and incorporated into the program?
- How has the code of conduct or its equivalent been incorporated into corporate policies across the organization? How does the organization measure that the code is understood and accepted across the organization? Has management taken affirmative steps to publicize the importance of the code to all of its employees?
- Does the compliance officer have sufficient authority to implement the compliance program?
- Has management provided the compliance officer with the autonomy and sufficient resources necessary to perform assessments and respond appropriately to misconduct?
- How is the board kept apprised of significant regulatory and industry developments affecting the organization's risk? How is the compliance program structured to address such risks?

Management Oversight

The OIG's hospital industry CPG and its draft supplement discuss the role of management in providing oversight to the compliance program. Most, if not all, corporate integrity agreements[1] require that the composition of a management compliance committee include senior management of the organization. These resources also suggest that operating units of larger systems also have their own compliance committees, where appropriate. Composition of these committees should include representation from across functional areas.

With regard to an organization's management compliance committee, the OIG's hospital industry CPG enumerates the following roles and responsibilities:

- Analyzing the organization's regulatory environment, the legal environment, and specific risk issues.
- Assessing policies and procedures that address applicable risk areas for inclusion into the compliance program.
- Working with applicable management to develop additional risk-specific policies and procedures as needed.
- Recommending and monitoring with relevant departments the development of systems of internal controls to carry out the organization's standards, policies, and procedures as part of the daily operations.
- Determining the appropriate strategy/approach to promote compliance with the program and detection of potential violations, such as through hotlines and other reporting mechanisms.
- Developing a system to solicit, evaluate, and respond to complaints and problems.
- Monitoring internal and external audits and investigations for the purpose of identifying troublesome issues and deficient areas and implementing corrective action.

An effectiveness study should examine whether and to what extent senior leadership is actively involved in bringing compliance issues "into focus," identifying risk areas for examination, suggesting mechanisms for resolution, and providing forums for individuals with expert knowledge in a given area to provide their recommendations.

Codes of Conduct and Compliance Policies

A code of conduct should clearly delineate the commitment to compliance by the organization. It should include the health care organization's mission, vision, and values. It should be distributed to and be comprehensible by all employees. It should be updated as applicable statutes, regulations, and federal program requirements are issued or modified. The document should make clear what is expected of employees when they encounter a suspected violation and set the proper ethical tone of how everyone associated with the organization is expected to behave in the workplace.

The OIG has identified the establishment of written policies and procedures as an element of an effective compliance program. The OIG has indicated that every compliance program should require the development and distribution of written compliance policies and procedures. These policies should provide tangible guidance and articulate the organization's commitment to comply with all federal and state laws and regulations, with an emphasis on preventing fraud and abuse. Compliance policies should be designed to accomplish the primary functions of: (1) providing guidance to the organization on critical compliance related areas; and (2) establishing a framework for the compliance program. These policies should be developed under the direction and supervision of the compliance officer and management compliance committee. A uniform process that ensures input from relevant employees should guide policy development, and approval should be received from appropriate management personnel.

Compliance policy documents should be distributed to, and be comprehensible by, all employees (e.g., translated into other languages and written at appropriate reading levels, where appropriate). These policies should cover:

- Program oversight
- Standards of conduct
- Problem resolution
- Employee training
- Monitoring and auditing procedures
- Medical directorship
- Compliance issue resolution
- Voluntary disclosure to third parties
- Hotline procedures
- Enforcement and discipline
- Confidentiality
- Records management

- Sanction screening
- Exit interview
- Vendor/dealer and distributor/agent agreements
- Communication between legal counsel and compliance officer
- Non-retaliation
- Conflicts of interest
- Billing compliance

Additional risk specific policies should be developed as the result of a comprehensive risk assessment. All compliance policies should be evaluated and updated as needed, and should be reviewed no less than on an annual basis.

An effectiveness study of the program documentation should examine:

- Whether policies have been developed to sufficiently cover the risk areas encountered by the organization;
- Whether these policies have been developed based on input from management;
- Whether and to what extent these policies contain stakeholder language such that ultimate responsibility for the risk area(s) mentioned is assigned to the appropriate subject matter groups; and
- Whether and to what extent these policies contain within them suggested control frameworks for consideration.

Since organizations may be held accountable for the activities indicated in written documentation, compliance policies, and procedures as well as the Code of Conduct should be clear, concise, and actionable. Such documentation should always be written so that all employees can read, understand, and carry out the applicable directives contained. Due in part to Health Insurance Portability and Accountability Act (HIPAA) requirements, some health care organizations are beginning to establish committees whose primary purpose is to regularly evaluate and approve key policies, particularly when substantive changes occur.

Due Care in Hiring—Sanction/Exclusion Screening

The unwitting retention of sanctioned or excluded individuals is a risk to which health care organizations do not want to be exposed and can do much to avoid. Exclusion means "a temporary or permanent debarment of an individual or entity from participation in any federal or state health-related program, in accordance with which items or services furnished by such person or entity will not be reimbursed under any federal or state health-related program."[2]

The OIG has been imposing exclusions since 1977. Medicare carriers and intermediaries are responsible for ensuring that no payment is made with respect to any item or service (other than an emergency item or service) furnished by an individual or entity during the period when such individual or entity is excluded from participation in Medicare. The exclusion also covers orders and referrals for items or services, as well as ownership or management of entities that provide items or services to Medicare beneficiaries.

While the federal government does not require organizations to also screen for individuals sanctioned at the state level, organizations should consider this information in order to make informed hiring and business decisions. In addition, organizations should assess their criminal background check procedures.

A risk assessment strategy regarding the nonretention of sanctioned individuals can include the following.

- Identification of key stakeholders in the process, including representation from human resources, purchasing, and credentialing;
- Inventory of entry points for new employees, vendors, and clinicians;
- A review of existing screening policies and procedures;
- A review/audit of actual screening practices;
- A review of employment applications to ensure that language includes inquiring whether individuals have been sanctioned or excluded from any federal or state programs;
- A review of vendor and clinical contracts to ensure that language includes inquiring whether individuals have been sanctioned or excluded from any federal or state programs;
- A review of board members, new and current employees, vendors, and physicians/care providers to confirm non-exclusion status;
- Evaluation of exclusion audit coverage to ensure compliance; and
- A report to the management compliance committee and board (periodically).

In addition, due to the events of September 11, 2001, the federal government has developed several newer databases for inclusion in the background checks. Health care organizations should evaluate whether and to what extent these databases are relevant to them.[3]

Compliance Communications

Another valuable tool to consider to enhance compliance program effectiveness is varied, proactive communication.[4] While compliance officers may be challenged in demonstrating that training has been effective, compliance officers can demonstrate that they have established and deployed varied mechanisms to communicate the regulatory compliance issues impacting the organization. Compliance officers can also attempt to measure employees' understanding and acceptance of these varied topics, including the compliance program itself, through quizzes and short interviews held with employees.

A compliance program is a behavioral program in that the desired result is the timely and appropriate identification and correction of issues. An effective program is based on a three-part theme. First, employees and other relevant individuals must understand that it is their affirmative and proactive duty to raise concerns in the workplace. Second, a healthcare organization must demonstrate tangible evidence of a "no-tolerance" policy for retaliation for such good faith reporting. Third, a health care organization must demonstrate that it will take timely action in response to issues or concerns raised. Communication strategies serve as the catalyst in establishing and maintaining a culture in the health care organization that trusts and supports the compliance program and its objectives.

The objectives of compliance program communication vehicles include the following:

- Informing individuals and entities how the compliance program works, including
  - Employees,
  - Vendors,
  - Physicians, and
  - Other business partners;
- Reminding employees of all of the various avenues for issue resolution;
- Ensuring that the compliance program remains at the forefront of people's attention;
- Providing education/discussion regarding regulatory risk areas identified by the OIG's CPGs and identifying and addressing new risks pertaining to particular departments or functions;
- Ensuring the program and its objectives are relevant at the working level; and
- Facilitating coordination among various work groups, especially as it pertains to problem resolution.

Avenues of compliance communication should include the following.

- New employee general compliance training;
- Refresher employee general compliance training;
- Development and promulgation of programmatic as well as risk-specific compliance policies;
- Subject matter (regulatory risk) compliance training;
- Human resources department communications;
- The compliance hotline (ethics line, voice mail system, etc.);
- The office of compliance communications;
- Performance improvement, subject specific or departmental meetings; and
- Senior (executive) management "town meetings."

The chain of command (lines of authority) should be integrated within these compliance communication channels. For example, some organizations might consider incorporating a general discussion of the compliance program when they conduct their regular monthly regulatory policy discussions. Departmental managers should be equipped to answer questions regarding the compliance program and forward any concerns or questions to the compliance officer. The compliance officer, in turn, should be able to document that these departmental meetings occurred, what the compliance regulatory topics were, and whether any follow-up actions were involved. In general, the compliance officer should be able to report to management and the board on the number of people trained on various topics, either through these departmental forums, Internet-based education, classroom training, or other forums.

Since both the Federal Sentencing Guidelines and the OIG's guidance documents emphasize the importance of training, compliance officers should be able to indicate how they have delivered the appropriate and relevant compliance training to the right people. Mitigating factors in the context of sentencing are important, of course, but the goal of compliance programs is to head off problems proactively, long before anyone is convicted, let alone sentenced. The OIG often views health care organizations that train as "trying hard" to operate in a compliant manner, and this can set the tone of an entire investigation and subsequent settlement negotiations. The goal would be to demonstrate a proactive method of identifying communication tools and resources based on a careful risk assessment.

Documentation is of critical importance. As with sanction screening, technology can allow the compliance officer to manage the process of demonstrating communication more efficiently. Internet-based compliance training is typically delivered via a "learning management system," which tracks, in various levels of detail, all the lessons taken, by whom, test scores, and the like. Aggregate data can make a compelling chapter in any assertion that one's compliance program is effective. Also, training reports by department can be a valuable management tool, allowing department managers to ensure that their subordinates are taking (and passing) the right compliance training lessons.

Other compliance communication effectiveness questions might include:

- Does the initial compliance training introduce the employees to the compliance officer? In other words, could the employee identify the compliance officer in person after the training?
- Is the initial compliance training lengthy enough to allow employees the opportunity to ask questions about the compliance program and participate in interactive discussions?
- Does the compliance officer measure whether employees understand the compliance training content?
- Does the organization have a formal compliance communication plan that includes programmatic education and regulatory risk education at the facility as well as departmental levels?

While no one communication mechanism can be looked upon as leading to an "effective program," all efforts together function as so many "threads" that weave together a fabric of compliance.

Compliance Hotlines and "Helplines"

Hotlines are one of many compliance communications tools, as they provide employees with another venue to raise potential compliance violations. Compliance hotlines serve as a method to raise issues in the workplace when employees have either exhausted other avenues or feel uncomfortable using those avenues. In addition, the recently modified Federal Sentencing Guidelines also suggest that the traditional hotline could become a "helpline" by offering an avenue for employee compliance research requests and not just avenues to report suspected compliance wrongdoing.

Matters reported through the hotline and other avenues should be documented and investigated promptly, utilizing internal or external counsel as necessary. A log should be maintained that records these matters, including the nature of any investigation and the results. A summary of this information should be included in reports to the organization's governing board, CEO and compliance committee. The summary could also include a risk rating for compliance hotline calls as well as an indication if the hotline call resulted in a more formal audit or monitoring activity.

The federal sentencing guidelines also suggest that hotlines allow the employee to maintain their anonymity and confiden-

tiality to the fullest permitted under the law. In other words, employees should not feel compelled to identify themselves. Any compliance hotline discussion should include a reminder to the employee of the organization's commitment to confidentiality and non-retaliation for good faith reporting.

Experience suggests that organizations will receive one to two hotline calls per month for each 1,000 employees. While human resource issues traditionally may have encompassed the majority of hotline calls, effective hotlines can demonstrate that substantial compliance related issues have been raised and resolved through this important element of a compliance program.

Effectiveness studies should consider:

- Whether all sources of inquiries are tracked to resolution;
- Whether inquiries are resolved and/or closed in a timely manner in accordance with written guidelines;
- Whether employees are receptive and open to the various hotline resources available to them;
- Whether corrective action identified has been carried out timely by the involved department; and
- Whether the hotline telephone number has been promulgated throughout the organization.

Disciplinary Actions

Effective compliance programs should include guidance regarding disciplinary action for all employees who have failed to comply with the organization's standards of conduct, policies, procedures, federal and state laws, or those who have otherwise engaged in wrongdoing that has the potential to jeopardize the organization's reputation as a reliable, honest, and trustworthy health care provider. All levels of employees should be subject to the same disciplinary action for the commission of similar offenses. Corporate officers, managers, supervisors, staff, and all other employees should be held accountable for failing to comply with, or the foreseeable failure of their subordinates to adhere to, the applicable standards, laws, and procedures.

Compliance should be an element of performance appraisal for all employees. The annual employee evaluation process should include an affirmative statement of adherence to the code of conduct. Compliance performance statements should also be developed for management focusing on their special responsibility to maintain the culture of the compliance program in identifying and resolving issues. For example, managers could be evaluated in terms of what percentages of their employees have attended training within a specific timetable, whether they conducted regular departmental compliance forums, and how they assisted in any hotline or helpline issues involving their area.

An effective compliance program must include disciplinary policies and procedures that are consistently applied throughout the organization. The types of disciplinary actions should be described along with mitigating/aggravating factors.

Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of a health care organization. Therefore, upon reports of reasonable indications of suspected noncompliance, the compliance officer or other management officials should initiate prompt steps to investigate the conduct in question to determine whether and to what extent a violation of applicable law or the requirements of the compliance program has occurred, and if so, take steps to correct the problem. Protocols should be formalized between the office of compliance and the organization's legal counsel regarding investigations or allegations of noncompliance with any law, rule or regulation.

Consistent Responses to Detected Offensives

No compliance program effectiveness evaluation would be complete without an assessment of how the organization has responded to known compliance violations. For example, if an organization knew of an overpayment, promptly changed procedures and even re-trained employees, but failed to refund the moneys, the compliance program would not meet the expectations of the regulators.

Due in part to Sarbanes-Oxley, health care organizations are developing and/or utilizing tools that document their systems of auditing and corrective actions taken. This process often begins with conducting a compliance risk assessment. This process looks at both the compliance risks affecting the organization, as well as the elements of the program itself. The risk assessment process should seek input and feedback from departmental managers, senior leadership, as well as the board. Once the risk assessment is completed, the compliance officer begins the process of identifying existing policies, practices, training, and audit coverage for the prioritized items.

When an offense is identified either through the planned system of audit coverage mentioned, through a compliance inquiry, or through some other mechanism (outside third-party review), the organization should be able to document how the corrective measures were appropriate given the level of compliance infraction. In addition, in those cases where overpayments are not necessary, but control weaknesses are identified, the compliance officer should establish a regular system of validating that management has undertaken measures to improve the controls in question.

Louis H. Feuerstein, CPA, is a partner in the Health Care Advisory Services practice of Ernst & Young LLP. He has been with Ernst & Young for more than 30 years and has extensive experience in coordinating and administering a broad range of business advisory, auditing and consulting projects for the firm's clients in the health care industry. He currently directs Ernst & Young's Corporate Compliance Program practice on a national basis.

Deborah Joslyn is a senior manager within Ernst and Young's Health Sciences Advisory Services practice. She is a national executive in the firm's corporate compliance practice. Since the mid-1990s, she has worked with numerous clients developing, implementing, evaluating and demonstrating effectiveness with their enterprise-wide compliance programs and efforts.

[1] CIAs can be found at www.oig.hhs.gov/fraud/cias.

[2] Federal Register October 26, 1999—45 CFR Part 61 Section 61.1.

[3] See "What you should know about screening excluded individuals and entities," by Louis Feuerstein and Deborah Joslyn, *CCH Health Care Compliance Letter*, Volume 7, Issue 2, January 26, 2004.

[4] See Evaluating and Improving a Compliance Program, Health Care Compliance Association, January 28, 2003.