CCH Healthcare Compliance LETTER

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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 Sharon Sofinski, Coordinating Editor, at sofinsks@cch.com. For more information about the CCH Healthcare Compliance Portfolio visit our online store at http://health.cch.com.

Preparing for the HIPAA security rule

by Catherine Hubbard, MA, Contributing Editor

With the April 21, 2005 compliance date for the HIPAA Security Rule looming, providers need to conduct a risk assessment, educate employees and ensure their technology conforms to the rule, according to Frank Bresz, senior manager of security and technology solutions, Ernst & Young.

Assessing risk. Conducting a risk analysis is one of the first steps toward understanding the best methods for addressing security issues. "Understand the risks and threats to your environment," he advised participants during a March 10 teleconference call sponsored by the Health Care Compliance Association.

If your organization is large, operates in several states and doesn't have firewalls between different departments, Bresz said, "It's likely people will be able to access information as it slides through the wires, one building to another." Although router technicians and other personnel would have the most access, it's feasible in a large organization that has conference rooms, wireless access and other connectivity that "data could be snooped while it is on the wire," he said.

The HIPAA Security Rule creates two categories of implementation specifications—"required" and "addressable." However, "addressable" does not mean that it is optional, Bresz cautioned. Instead, the rule provides flexibility in implementing a particular strategy for addressing an information security item, while not requiring you to implement a particular level of security, such as encryption.

Also, Bresz warned, if it's reasonable to anticipate that that someone can gain access to information and the organization did not take the proper precautions, it could be viewed as being non-compliant, Bresz warned. "It's important to understand the localized threats to your environment, whether they be technological threats, physical threats or administrative threats and to take appropriate measures to protect yourself," he said. "The further up you go in the electronic world, the more likely it is that there will be additional threats to your information that were not there when you had simple manual processes for controlling access to information," he observed.

In deciding what to implement with regard to addressable items, organizations should look at their own internal risk analysis, and understand the risk of litigation and what other controls are in place to prevent security breaches. It should also take into account the cost of implementing a particular security measure, Bresz said. However, he added that the cost alone can't be used to justify not implementing a security element.

Regarding security management, the rule requires providers to perform a detailed risk analysis and have an ongoing risk management program. "A detailed analysis will examine how various threats can impact information security in your environment," Bresz said.

Corporations also should review any mitigating controls, understand the relationship between those threats and the mitigating controls and make sure any residual risk aligns with both HIPAA and the organization's tolerance for risk, he explained. "It's important that a particular security person within your organization has responsibility for administering the security program so that all elements of the HIPAA security regulations are met," he said.

Promote security awareness. Rather than require employees to learn about new laws and regulations, Bresz advised, organizations should instruct them to follow the corporate policies and procedures. "Trying to educate employees on all the regulatory minutia is difficult and it's much more simple if you allow them to understand your corporate policies," he said.

Employees should understand the security risks so that they can report incidents to the proper person in the company, Bresz said. The organization should have in place a plan showing what actions to take and what other organizations to notify in case there is a breach, he noted.

Bresz also advised organizations to examine how they control information stored on removable media. For example, if an employee has personal health data stored on a diskette, there must be controls to ensure the information is not improperly disclosed, he said. One way to make sure that doesn't happen is to encrypt information on the disk or discourage employees from reusing disks, he said. Any remnants of PHI on disks must be removed before they are discarded, he added.

Seeing the foreseeable. The Final Security Rule requires that all covered entities must ensure the confidentiality, integrity, and availability of all electronic protected health information. Organizations must protect against any reasonably anticipated threats or hazards to the security or integrity of such information. "A reasonably anticipated threat is something that must be developed as you begin your risk analysis process," he said. "If there is a complaint against your organization and a finding that this was a reasonably anticipated threat, then it will increase the likelihood that you'll be fined," he said.

"If it's reasonable to anticipate that that someone can gain access to information and the organization did not take the proper precautions, it could be viewed as being non-compliant."

Choose HIPAA-compliant technology. Complying with the HIPAA Privacy Rule does not necessarily make organizations compliant with security regulations, but implementing privacy standards may help reduce the cost of implementing the security standards, Bresz said. A lot of organizations have already purchased technology to help protect privacy, he noted. However, any controls put in place for the Privacy Rule must comply with the Security Rule. "All of those controls, where they are required, must be put in place," he said.

Bresz also recommended organizations:

- Have solid and robust compliance metrics for measuring the effectiveness of an information security program on an ongoing basis.
- Encourage employees to create a strong password. These should be short enough to remember, but long enough to prevent attempts at cracking it. He recommended setting passwords between six and eight characters with a mixture of characters.
- Make sure all policies, procedures and programs help all employees and people who interact with electronic PHI to perform their job in a way that will allow them to easily be compliant.
- Make sure that employees who are terminated or lose a job function do not have the same access to E-PHI they had before the change. ■

CCH Washington Bureau, March 12, 2004

CCH Healthcare Compliance Letter

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False Claims Act settlements totaling over $15 million announced

by Sharon Sofinski

The Department of Justice recently announced three settlements, totaling more than $15 million, to resolve allegations of False Claims Act violations.

Johns Hopkins settlement. Johns Hopkins University and Johns Hopkins Bayview Medical Center have agreed to pay the United States more than 2.6 million to settle allegations that they violated the False Claims Act, U.S. Attorney Thomas M. DiBiagio has announced.

The allegations center on the institutions' claims related to federally sponsored research grants that were awarded from 1994 through 2000. The government charges that:

- John Hopkins researchers overstated the percentage of work effort they were able to devote to the grants.
- When drawing down funds on the grants, Johns Hopkins overstated the percentage of effort that personnel had actually worked on the grants.
- By applying incorrect fringe benefits rates to the grants, Johns Hopkins obtained federal money that it was not entitled to.

The cause of the overstatements, according to the charges, is partly due to the institutions' "failure to maintain adequate compliance mechanisms" to reconcile proposed efforts with the efforts actually devoted to the grants. Faye Grau, a Johns Hopkins employee, filed the whistleblower lawsuit in May 1999 under the False Claims Act. Grau will receive more than $400,000 of the total recovery.

Johns Hopkins denies the charges and has agreed to take any corrective actions needed to ensure the integrity of its grants process in the future. It will work with the NIH Division of Grants Compliance and Oversight.

DiBiagio stressed that "The United States must maintain the integrity of the grant application and funding process for research. It is important that universities and other institutions properly use federal research funds."

For a copy of the U.S. Attorney's press release on the Johns Hopkins settlement, go to http://www.usdoj.gov/usao/md/press_releases/press04/JHUsettlePR.pdf.

Baptist Health System settlement. Alice H. Martin, U.S. Attorney for the Northern District of Alabama, announced that Baptist Health System, Inc. has paid $1.3 million to settle a whistleblower suit brought by Teri Flanagan, a former Baptist employee.

Flanagan charged that Baptist's hospitals submitted claims to Medicare for outpatient physical or occupational therapy services without proper physician certification or plan of care certifying that the services were necessary. Under the *qui tam* provisions of the False Claims Act, Flanagan will receive $260,000 of the total recovery for bringing the suit. For a copy of the U.S. Attorney's press release, see http://www.usdoj.gov/usao/aln/Pages/newsreleasesmain.html.

Quest Diagnostics settlement. Quest Diagnostics, a large operator of clinical diagnostic laboratories, has agreed to pay $11.35 million to settle allegations that one of its subsidiaries and two of its predecessor companies defrauded the Medicare program by improperly billing Medicare and performing medically unnecessary tests at its laboratories. Quest has denied the allegations. The U.S. Attorney's press release is at http://www.njusao.org/files/ques0301_r.htm.

According to the complaint, from 1990 to 1997, Quest submitted claims to Medicare and MediCal for medically unnecessary tests, including:

- Apolipoproteins, included in test profiles and panels designed to test for coronary conditions;
- Urine microscopy exams; and
- Calcium and parathormone (PTF) tests.

Quest is also alleged to have improperly billed for unlisted test panels when more specific tests should have been billed.

Kevin Spear, a former sales representative for Unilab Corporation, a Quest subsidiary, filed the whistleblower lawsuit and will receive approximately $2.4 million of the settlement.

Dana Corrigan, Acting Principal Deputy Inspector General for the Department of Health and Human Services (HHS), stressed, "We are committed to protecting the integrity of the taxpayer-funded Medicare Trust Fun. Under this settlement, misappropriated Medicare funds—plus damages—will be returned to the program." The Office of Inspector General of HHS participated in all three investigations. ■

CCH Chicago Bureau, March 12, 2004

Accreditation of human research programs: A new wave

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

This article is the fourth in a series devoted to the ethical and regulatory compliance issues associated with the provision of clinical trial services. The previous articles addressed compliance issues related to (1) billing, claims submission and anti-kickback concerns,[1] (2) protection and safety of human participants in medical research,[2] and (3) relationships between funding agencies, individual researchers and their institutions.[3]

For healthcare providers, the process of accreditation of health care programs is not new. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)[4] has been accrediting hospitals since 1951 and, more recently, other healthcare organizations such as long term care facilities, home health agencies, assisted living facilities, ambulatory care services and medical laboratories.

What is new is the emphasis that increasingly is being placed on the accreditation of clinical research programs. Until now, clinical research programs have not been accredited as separate programs or processes. Although the Department of Health and Human Services' Office of Human Research Protections (OHRP) is charged with oversight responsibilities for research programs, recent tragic cases,[5] coupled with the rapid growth of medical research and increased demands for research participants' protection, have provided the impetus necessary to create voluntary programs for accrediting research activities.

While the goal of any healthcare accreditation process is to increase the quality of care delivered by improving the systems required to provide that care, clinical research programs also have the specific goal of protecting the rights and welfare of the individuals who participate in medical research programs. The advantages to a research institution for participating in a voluntary accreditation process can be many, including:

- reducing potential compliance risks to the research organizations and health risks to human participants in the research studies;
- increasing public confidence in the research process;
- increasing a research program's credibility in the eyes of its potential sponsors;
- increasing the research program's ability to recruit participants; and
- decreasing the research program's risk of suspension or debarment if a violation or serious deficiency is detected.

Currently, two different organizations provide accreditation programs for medical research programs:

- Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP); and
- Partnership for Human Research Protection, Inc. (PHRP), a joint program with the Joint Commission on Accreditation of Health Care Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA).

Both accreditation programs are relatively new and are *voluntary*. They address the principal issues identified in the 2001 Institute of Medicine's report, *Preserving Public Trust: Accreditation and Human Research Protection Programs*,[6] including:

- organizational responsibilities;
- Institutional Review Board (IRB) structure and operations;
- consideration of risks and benefits; and
- informed consent.

While both accreditation programs address the protection of human subjects outlined in federal regulations, they differ in their approach and detail. The AAHRPP program provides for standards that meet or exceed federal regulations but their approach simplifies the process. The JCAHO/NCQA process is more complex in its approach, although it is very similar to other JCAHO accreditation methodologies, which are very familiar to most health care providers. Its standards also meet or exceed federal guidelines.

Association for the Accreditation of Human Research Programs (AAHRPP)

The Association for the Accreditation of Human Research Programs is a nonprofit organization that offers accreditation to institutions engaged in research involving human participants. AAHRPP was incorporated in 2001 and now accredits approximately eight to ten research programs or organizations. It utilizes a model of peer review and education as its means of ensuring compliance with human rights protections for research participants and other regulatory requirements. AAHRPP has adopted nine principles that serve as the foundation for the structure and content of its accreditation standards, including:[7]

- Regulatory compliance is a minimal expectation for a human research protection program.
- Protecting the rights and welfare of human research participants must be a research organization's first priority.

Beyond assessing compliance with applicable regulations, accreditation standards should promote a research environment where ethical, productive investigation is valued.

- Accreditation must approach the human research protection program from a broad organization perspective, moving beyond a narrow focus upon Institutional Review Board (IRB) operations to examine whether policies and procedures of the organization as a whole result in a coherent, effective scheme for the protection of human research participants.
- The accreditation process should be flexible and responsive to changes in federal and state regulation of research.
- Accreditation should be primarily an educational process involving collegial discussion and the provision of constructive feedback.
- Standards should be performance-based, assessed through an evaluation scheme that is sufficiently detailed to support the accreditation process, yet capable of effective and efficient implementation.
- Standards should be applicable to human research protection programs across the full range of settings.
- The accreditation process should provide a clear, understandable pathway to accreditation, along with equally clear pathways for appeal and the remediation of identified shortcomings.
- Standards should promote the development and implementation of outcome measures that can provide a basis for demonstrating quality improvement over time.

AAHRPP's actual accreditation standards are designed to assist organizations in meeting their ethical and legal requirements for protecting human research participants. AAHRPP incorporates five domains into its accreditation process, representing areas of responsibility that must be addressed in any human research protection program: organization, research review unit, investigator, sponsor and participant.[8] Meeting the requirements for all five domains is the responsibility of the organization that is seeking accreditation.

The AAHRPP accreditation process includes several steps:[9]

- Self-assessment;
- On-site evaluation;
- Council review; and
- Notification of accreditation status.

Any AAHRPP accreditation granted to an organization is for three years, after which the organization must be re-evaluated in order to retain its accreditation.

The Partnership for Human Research Protection (PHRP)

The Partnership for Human Research Protection is a collaborative effort between the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA). By providing a uniform set of standards that complement regulatory efforts, PHRP provides support for organizations in their continuing medical research efforts through assuring the protection of volunteer human subjects who participate in these studies. The program focuses on best practices and continuous improvement, rather than on compliance with minimal standards.

The accreditation standards focus on the following areas:[10]

- Organizational responsibilities;
- Institutional Review Board structure and operations;
- Consideration of risks and benefits; and
- Informed consent.

The PHRP accreditation surveys include the use of a web-based tool (known as the Interactive Survey System) that organizations use to self-evaluate and then report their findings for PHRP review; off-site review of the evaluation results and analyses of supporting documentation; and on-site reviews conducted by a team of PHRP surveyors. The team of surveyors includes research clinicians and other professionals experienced in biomedical research. The on-site review usually lasts two to three days.

There are two principal components of the Interactive Survey System: the first is the Standards and Guidelines component and the second is the Survey Tool component. Standards and Guidelines are appropriate for use by an organization or an individual wishing to learn more about the accreditation process.[11] They contain:

- The complete standards;
- Explanations of exactly how PHRP evaluates and scores the standards;
- Specific scoring rules for each element;
- A list of data sources needed to support scoring;
- Explanations of the scope of review for each element; and
- Additional explanations and examples to help guide survey preparation.

The Survey Tool includes all of the features of the Standards and Guidelines and the interactive screens used by organizations to enter data and information for survey purposes.

PHRP awards accreditation for a maximum of three years and requires annual reporting to assess compliance by the accredited organization.

What does this mean for organizations that conduct human research programs?

That there are two choices for research accreditation available to medical research programs means that there likely will be a strong impetus for all research programs to participate in one, thus making accreditation a *de facto* "standard." Accreditation

provides the ready-made "stimulus" to get institutional leaders, as well as the medical researchers, "on board" and working to create more effective, more compliant research programs.

Accreditation will help to provide more uniformity between research institutions because standards, best practices and outcome measures will be similar. Accreditation should also bolster public confidence in medical research programs by providing more interest and participation in the clinical trials process, which ultimately provides a benefit to all citizens.

The downside of voluntary accreditation is that it costs money. Both accrediting organizations charge a fee for conducting the accreditation, as well as charge an annual "membership" fee. For an organization seeking accreditation, adding staff will likely be necessary to accomplish all the tasks and reporting requirements. Staffing expenses and fees can mount up although, when viewed against the costs of a significant compliance violation, actual accreditation costs may be minimal. Some of the overhead costs for accreditation may be able to be folded into the budgetary requests for grant monies.

Resources for more information

For more information on accreditation of human research programs, the following websites may be of interest:

- Association for the Accreditation of Human Research Programs (AAHRP)
  http:// www.aahrpp.org
- Partnership for Human Research Protection (PHRP)
  http://www.phrp.org
- Citizens for Responsible Care and Research (CIRCARE). CIRCARE is a human rights organization dedicated to the protection of human subjects in research and medical treatment. CIRCARE is especially concerned with the protection of vulnerable subjects such as the mentally incapacitated, children, seniors, the homeless, and the poor. By raising public awareness of human subject vulnerability in research and treatment, CIRCARE works to prevent unethical practices.
  http:// www.circare.org
- Institute of Medicine, The National Academy of Sciences (IOM). The Institute of Medicine serves as advisor to the nation to improve health. As an independent, scientific advisor, the Institute of Medicine provides advice that is unbiased, evidence-based, and grounded in science. It has produced two recent reports on accreditation of human research programs and the protection of research participants.
  http://www.iom.edu.

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. Ms. Brent is author of Understanding Reimbursement for Investigational Drugs and Devices, published by CCH, Inc., April 2003, and is a member of the CCH's Healthcare Compliance Editorial Advisory Board. She is also a member of HCCA's Region 1 Program Planning Committee.

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 Patricia Brent, J.D., M.P.H., "Compliance Issues Related to the Protection and Safety of Human Participants In Medical Research Studies," *CCH Healthcare Compliance Letter*, Vol. 6, Issue 16, August 18, 2003.

3 Patricia Brent, J.D., M.P.H., "Relationships Between Research Funding Agencies and Individual Researchers and Their Institutions," *CCH Healthcare Compliance Letter*, Vol. 6, Issue 17, September 5, 2003.

4 See Joint Commission on Accreditation of Healthcare Organizations, http://www.jcaho.org.

5 18-year-old Jesse Gelsinger suffered from a rare genetic disease that caused him much discomfort and seriously affected his lifestyle. Gelsinger died in 1999 after volunteering to participate in an experimental gene transfer treatment at the University of Pennsylvania. It was alleged that clinical investigators violated several federal regulations regarding human subject protections, including failure to disclose financial conflicts of interest, to follow established clinical protocols and to report adverse effects of experimental procedures (*Washington Post*, Nov. 4, 2000, p. A4). In 2001, Ellen Roche, a healthy 24-year-old clinical trial volunteer, died at Johns Hopkins University during a study testing the effects of an asthma drug. It was alleged that JHU investigators failed to provide informed consent and deviated from the FDA's approved usage for the drug study (*Washington Post*, August 30, 2001, p. B3). Also in 2001, Elaine-Holden-Able died at Case Western Reserve University during an Alzheimer's clinical trial designed to study amino acid metabolism. A clinical trial volunteer, Ms. Holden was a 70-year-old retired nurse. It was alleged that CWRU researchers failed to obtain proper informed consent and they failed to provide proper treatment immediately after Ms. Holden became ill (*Washington Post*, Jan. 12, 2002, p. A3).

6 *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs*, Institute of Medicine, National Academy of Sciences, April 17, 2001, Washington, D.C.

7 See *Principles for Accreditation of Human Research Protection Programs*, Association for the Accreditation of Human Research Protection Programs, Inc. at http:// www.aahrpp.org.

8 See *The Five Domains of Standards*, Association for the Accreditation of Human Research Protection Programs, Inc. at http:// www.aahrpp.org.

9 See *Accreditation Step-by-Step*, Association for the Accreditation of Human Research Protection Programs, Inc. at http://www.aahrpp.org.

10 See Joint Commission on Accreditation of Healthcare Organization's *Partnership for Human Research Protection, Inc., Accreditation Program* at http://www.jcaho.org.

11 See *PHRP Interactive Survey System FAQs*, Partnership for Human Research Protection, Inc., http://www.phrp.org.

Courts examining health quality effects in antitrust cases, FTC attorney says

by Catherine Hubbard, MA, Contributing Editor

Defendants in antitrust cases need to start proving their exclusive contracts and other arrangements have not harmed health care quality, according to David Hyman, special counsel to the Federal Trade Commission. "Courts are getting more skeptical of the general level assertions about quality," he told attorneys during a recent telephone conference sponsored by the American Bar Association's Health Law Section and the Center for Continuing Legal Education. "If you want to rebut [a claim], having actual evidence is much more effective," he said.

Hyman noted that in past court cases, defendants rarely have presented specific data on health care quality, in part because it's so difficult to do. "Measuring quality certainly is a challenge," he said. "The challenge is, how do you get expert testimony in a timely enough way to actually have it affect the case?" he said. It will be difficult, expensive and time consuming for researchers to access and process the data quickly. However, he predicted antitrust lawyers will need to start hiring health services research experts "much more frequently" than they have in the past.

Plaintiffs almost always raise quality issues, Hyman pointed out. "Almost any incursion of antitrust on professions has been met by anguished cries that you will eliminate high quality care by introducing market competition," he observed. But courts have not grappled effectively with quality claims, he said. They have not answered the question, "How do you balance price and quality, encourage innovation and factor access and trust into the equation?" he said.

Also, most cases have involved private claims over staff privileges, such as people who had been denied membership on a medical staff or those who were closed out when a hospital moved to an exclusive contract, he said. "There are lots of these cases that are brought, but they're not doing very well," he said, noting that only about one percent succeed.

"It's a question of quality," Hyman said, adding that while the medical profession is interested in preserving professionally pre-determined restrictions on market processes, antitrust lawyers are trying to eliminate them. "This frames a series of coming battles that will map out the future of antitrust law in health care," he predicted. ■

CCH Washington Bureau, March 10, 2004

Rx pricing antitrust, racketeering litigation goes forward

by Suzanne Szymonik, JD, Contributing Editor

Employee benefit plans may pursue federal racketeering and price-fixing conspiracy charges against numerous prescription drug companies that allegedly overstated average wholesale prices (AWPs) for their drugs. The plans alleged that the drug companies created a spread between actual costs to providers such as doctors and costs to Medicare Part B beneficiaries, and provided fraudulent kickbacks, discounts, and rebates to encourage pharmacy benefit managers to put certain drugs on their formularies. A February 24, 2004, preliminary order from the U.S. District Court for the District of Massachusetts threw out charges against one defendant, Hoffman-LaRoche, Inc., but permitted charges to stand against virtually all other major drug companies.

RICO charges not dismissed. The district court will permit a trial on Racketeer Influenced and Corrupt Organizations Act (RICO) charges. Although no conspiracy between drug companies and publishers of AWPs was established (because publishers have no common interest with drug companies and a spread is irrelevant to their financial well being) a connection between drug companies and pharmacy benefit managers was sufficiently and specifically alleged by complaining employee benefit plans that described a common fraudulent purpose, systematic linkages, common communication networks, and regular meetings. Allegations about particularly high AWP spreads for multi-source drugs, i.e. generic drugs made by three or more manufacturers, also may be tried. The benefit plans alleged that spreads for multi-source drugs sometimes resulted in AWPs 50,000 percent over actual costs. ■

In re Pharmaceutical Industry Average Wholesale Price Litigation, U.S. District Court for the District of Massachusetts, Feb. 24, 2004

Survey reveals slight drop in healthcare executive/manager commitment

The latest Healthcare@Work survey by AON Consulting and the American Society for Healthcare Human Resources Administration (ASHHRA) has revealed that U.S. health care employees were a little less committed to their organizations in 2003 than they were in 2002. Executive leadership and manager/department head groups were responsible for most of the drop in the survey's commitment index, which fell from 91.5 to 91.0. The report noted that, "[W]hile their scores are still quite high at 100.6 and 97.9 respectively, there is more pressure than ever before for these individuals to perform." The results were released on February 9, 2004.

The report indicates that the following areas require further investigation for their possible role in the decrease in commitment: continuing staffing shortages, growing government regulations, cost containment pressures and rising patient expectations. "Health care leaders are expected to achieve results and these combined pressures could lead to high levels of frustration and burnout," the survey said. The full Healthcare@Work report can be found at http://www.hospitalconnect.com/healthcareworkforce/jsp/whatsnew.jsp under "New Resources."

Sentencing Guidelines

HCCA voices concerns about proposed changes to sentencing guidelines

by Sharon Sofinski

In a letter to the U.S. Sentencing Commission dated February 16, 2004, The Healthcare Compliance Association (HCCA) Executive Committee commented on the proposed changes to the Federal Sentencing Guidelines relating to compliance programs.

HCCA supports the proposed changes overall, lauding the changes' increased emphasis on the importance of compliance programs and the compliance officer's role as a member of senior management; the changes that provide more guidance and direction on compliance programs; and the changes that address the compliance officer's need for authority and resources to do the job.

However, HCCA suggests revisions to two of proposed changes:

- The proposed addition to §8B2.1(b)(2), which states that the person responsible for the compliance program must "ensure the implementation and effectiveness of the program."

  According to HCCA, this change implies that the compliance officer alone will be held responsible for the success or failure of a compliance program. Stressing that "this amendment may not reflect the fact that compliance can only be achieved if the operating management of an organization (at all levels) performs the roles and responsibilities assigned to it through the compliance program," HCCA proposes that the language be modified to clarify that management must be involved.

"This amendment may not reflect the fact that compliance can only be achieved if the operating management of an organization (at all levels) performs the roles and responsibilities assigned to it through the compliance program."

- The proposed changes regarding the treatment of organizations that encounter compliance problems even though they have a compliance program in place.

  HCCA believes that these changes are indeed a step in the right direction, but that even more can be done to promote effective compliance programs. HCCA states in the letter, "As drafted, the proposed amendments create a *rebuttable* presumption that the compliance program *was ineffective* we would proposed a rebuttable presumption that the program *is effective* if it is the organization that discovers and bring the offense to the attention of the government."

The U.S. Sentencing Commission's proposed changes to the guidelines were published in a notice in the December 30, 2003 Federal Register (68 Fed. Reg. 75339; see http://www.ussc.gov/2004guid/rfJan04.pdf). All written comments on the changes were due to the Sentencing Commission on March 1, 2004. To read the full letter from HCCA's Executive Committee, see http://www.hcca-info.org/eseries/StaticContent'USSCletter.pdf. ■

CCH Chicago Bureau, March 12, 2004

Fraud & Abuse

Co-insurance waivers for municipal ambulance services

by Suzanne Syzmonik, JD, Contributing Editor

A proposed waiver of Medicare copayments and deductibles for ambulance services provided by a municipal fire department's emergency medical service (EMS) only to the municipality's residents would not violate the anti-kickback provisions of the Social Security Act. HHS' Office of Inspector General (OIG) will permit the proposed arrangement, according to an OIG Advisory Opinion issued on March 1, 2004.

Similar fire department cases. In this case, a city adopted an ordinance, proposing to fund its EMS ambulance services through Medicare and other insurance billing as well as a monthly utility fee placed on residents' water bills, but not through any out-of-pocket costs to residents. Although the OIG cautioned that its decision is limited to the facts presented—in recent years, it has issued a number of similar advisory opinions regarding municipal fire department's "insurance only" billing practices (See ¶150,169; ¶150,170; ¶150,189; and ¶150,196). OIG stated that its concern about potentially abusive waivers of Medicare cost-sharing amounts under the anti-kickback statute is longstanding.

CMS Manual exception. According to the OIG opinion, "insurance only" billing implicates the anti-kickback statute because it constitutes a limited waiver of Medicare cost-sharing amounts, and therefore, could be an impermissible offer of "remuneration" for a service reimbursable by a federal healthcare program. There is a special rule, however, for providers owned and operated by states or municipalities such as fire departments; the OIG rested its advisory opinion on the special rule. The exception is published in CMS' Medicare Benefit Policy, Chapter 16, §50.3. It provides that state or local government entities that charge patients only to the extent of their Medicare and other health care insurance coverage are not viewed as furnishing free services and may receive program payment.

Bona fide residents. The OIG cautioned that the proposed waiver is only permissible if given to bona fide city residents. This opinion does not apply to cost-sharing waivers based on criteria other than residency or to city contracts with outside, private ambulance suppliers. ■

OIG Advisory Opinion 04-02, March 1, 2004, ¶150,214