CCH Health Care Compliance LETTER

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HHS backs Florida in price gouging suit

by Anuradha Gupta, JD, Contributing Editor

The Department of Health and Human Services (HHS) filed a brief to support the State of Florida's prosecution of price gouging by distributors of the flu vaccine. HHS Secretary Thompson extended this support to all states in a letter to attorneys general nationwide as they crack down on any price gouging or other irregularities regarding the flu vaccine. Florida officials announced that the defendant in its case agreed to no longer buy or sell flu vaccines and surrendered its remaining flu vaccine to the Florida Department of Health. HHS has been coordinating with the National Association of Attorneys General to report and combat price gouging throughout the country.

Price gouging punishment. In his letter, Secretary Thompson addressed his concern over the national shortage of the flu vaccine and the harmful, price-gouging efforts of "unscrupulous people." Secretary Thompson also outlined the brief filed in Florida, noting the terrible impact of the abuse on the nation's high-risk population who are in great need of the flu vaccine. He emphasized that anyone engaged in price gouging should be punished to the full extent of the law, and any state attorney general who needs the HHS' assistance should contact the HHS General Counsel.

Supply of antivirals. Attorneys general should also be on guard against potential price gouging with regard to antiviral medicines that can be used to prevent and treat the flu. These medicines—namely amantadine, rimantadine, oseltamivir/Tamiflu and zanamivir—can effectively protect the public from the flu and its complications. While there is a healthy supply of these medicines, demand for them may also become high and lead to price gouging.

Counterfeit medicines. Finally, Secretary Thompson stressed watching for counterfeit medicines and false claims that certain products can help prevent or treat the flu. It is critical to work with other officials within the state to ensure that the available vaccines and antivirals are distributed without price gouging to our citizens who need them the most. The full text of the brief is available online at http://www.hhs.gov/flu. ■

CCH Chicago Bureau, November 8, 2004

PhD excluded from participation in federal health care programs

by Susan A. Marks, Esq., Contributing Editor

A licensed psychologist was properly excluded from participation in Medicare and Medicaid for a period of ten years because he was convicted of an offense related to the delivery of care.

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.

From October 1995 to June 1999, the psychologist operated a private psychological counseling practice in Las Vegas, Nevada. In the fall of 1999, the State of Nevada Office of Attorney General began an investigation into his practice. Finding probable cause, the investigators issued a search warrant and seized the psychologist's records. Their finding was that the psychologist was in possession of public money belonging to the state, had made improper and inaccurate billings and had kept public money to which he was not entitled. He was charged with unlawful use of public money. The psychologist pleaded guilty, was convicted, and was ordered to pay restitution in the amount of $75,000 to the state. Subsequently, the inspector general (IG) excluded him from participating in Medicare, Medicaid and all other federal health care programs as defined in section 1128B(f) of the Social Security Act (Act). See, ¶16,457B-2.

Conviction program related. The Social Security Act requires that an individual be excluded from participation in Medicare, Medicaid, and all other federal health care programs when convicted of a criminal offense related to the delivery of care [Act, § 1128(a)(1)]. See, ¶16,457B. During the review of his exclusion, the psychologist argued that his conviction of unlawful use of public money had no relationship to the Medicaid program. The administrative law judge (ALJ) stated that a relationship to Medicaid is not an element of the offense, but that fact was not dispositive. The psychologist did not have to be convicted of Medicaid fraud. He only needed to be convicted of an offense related to delivery of care under the Medicaid program. His conviction was related to the care he rendered because there was a common sense connection between them. He was billing Medicaid for services rendered and had paid restitution to Medicaid. He was convicted within the meaning of the Act. The psychologist argued that he was convicted for "not paying attention"to how claims were submitted and that he did not intend to submit incorrect claims. However, intent is not an element of the crime he was convicted of and is not required for a finding that the conviction was program related.

Exclusion reasonable. An individual or entity convicted of a criminal offense related to the delivery of an item or service under Medicare or Medicaid must be excluded for not less than five years [Act, § 1128(c)(3)(B); 42 C.F.R. § 1001.102(a)]. See, ¶22,188.102. The IG may impose an exclusion for a longer period if certain aggravating factors are present [42 C.F.R. §1001.102(b)]. Here, the IG has proven that there are two aggravating factors. First, the criminal acts of the psychologist caused a loss of more than $5,000 to a government program. Since the psychologist was required to pay restitution to the Nevada Medicaid program in the amount of $25,965.06, the loss was well in excess of $5,000. Second, the psychologist engaged in criminal acts for a period of one or more years. Because his practice engaged in improper billing from October 1995 through June 1999, this factor is proven. The psychologist's argument that he was not paying attention to how claims were being submitted was not valid because he had plenty of time to detect and correct his office's billing errors. The ALJ also noted that many times defendants enter plea agreements only to get the matter behind them and are unaware of the pleas's effect on their future ability to continue their careers. But, in this case, the psychologist signed a plea agreement and acknowledged his awareness that he could be excluded from participating in the provision of health care services in governmental associated health care programs.

"The psychologist's argument that he was not paying attention to how claims were being submitted was not valid because he had plenty of time to detect and correct his office's billing errors."

Mitigating factors. If aggravating factors are present, then the IG must consider specified mitigating factors to determine whether the term of exclusion should be shortened [42 C.F.R. §1001.102(c)]. The psychologist did not allege or prove the existence of mitigating factors that might have reduced the period of his exclusion. The mitigating factors are defined by the regulations and operate as evidentiary rules. The fact that the psychologist argued that he did not intend to submit inaccurate bills or cause

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a loss to any government program was not a specified mitigating factor. Only evidence related to a specified mitigating factor may be used in making a determination of his trustworthiness and since there is no evidence, there is no basis to reduce the period of his exclusion. ■

HHS Dept. Appeals Board Decision, Sept. 20, 2004,¶300,089

Nurse's ten-year exclusion was reasonable

by Anuradha Gupta, JD, Contributing Editor

The Inspector General (IG) properly excluded a nurse from participation in the Medicare and Medicaid programs for ten years. The nurse pled guilty and was convicted in a Nevada state court of "obtaining money, property, rent or labor by false pretenses," a criminal offense related to the delivery of an item or service under the Medicaid program.

Proper exclusion. The nurse, who was employed in the billing department of a company participating in Medicare and Medicaid programs, acted with knowledge that the billings contained material inaccuracies and the services billed for could not be wholly substantiated. Her conviction arose from the company's submission of improper claims. The nurse's argument that her conviction had no relationship to the Medicaid program fails, because only a connection to the delivery of an item or service under the Medicaid program is required.

Reasonable exclusionary period. The nurse argued that the ten-year exclusion period was unreasonable. The law requires a minimum five-year exclusion for any individual convicted of a crime related to the delivery of an item or service under the Medicare program. However, the length of the exclusion may be increased based on aggravating factors or decreased based on mitigating factors. In aggravation of her exclusion was her conviction for criminal acts occurring over a period of one year and that those acts caused a loss of more than $5,000 to a government program, justifying a ten-year exclusion. ■

Colosimo v. Inspector General HHS Departmental Appeals Board, Dec. No. CR1226, Sept. 30, 2004, ¶300,088

Sentencing Guidelines

Sentencing Guidelines: What the health care industry needs to know

by Frank Sheeder, Esq.

The Federal Sentencing Guidelines are usually (and fortunately) the furthest thing from a compliance professional's mind. But (unfortunately) the federal Sentencing Guidelines form the underpinnings of many of the compliance doctrines and practices with which members of the health care industry work every day. In today's enforcement environment and in light of recent statutory changes and proposed amendments to the Organizational Sentencing Guidelines, the health care industry must now pay even more attention to them.

Background. Congress created the United States Sentencing Commission (USSC) in 1984. The USSC is responsible for promulgating federal Sentencing Guidelines. Congress' goal in forming the USSC was to create a federal sentencing structure that would diminish disparate treatment of criminal offenders. In 1987, the USSC issued federal Sentencing Guidelines for individuals. In 1991, the USSC issued federal Sentencing Guidelines for Organizational Defendants (the "Organizational Sentencing Guidelines"), which apply to organizations that are convicted of federal crimes. They allow for imposing fines and restitution and placing the organization on probation.

The Organizational Sentencing Guidelines allow organizations to mitigate sentences if they can demonstrate adherence to "7 elements" that demonstrate an effective compliance program. The 7 elements are also the underpinning of the OIG's various Compliance Guidances and the

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Consent to treatment as a compliance issue

by Fay A. Rozovsky, JD, MPH, and James R. Woods, MD

In this article, the authors present a scenario that illustrates how the clash of compliance-based laws like EMTALA, human research regulations, state advance directive laws, and the Patient Self-Determination Act can result in litigation.

T.J. smashed his motorcycle into a concrete barrier. The police estimated that he was traveling at 85 miles per hour in a 50-mile-per-hour zone. Although T.J. was wearing a helmet, he was not wearing a traditional leather jacket or pants. T.J.'s helmet flew off when he landed on the ground.

T.J. was transported by helicopter to a nearby high-level trauma center. He arrived unconscious. His vital signs were unstable, and the ER team determined quickly that he had sustained severe internal injuries, broken ribs, and compound fractures to both his legs. When he was thrown from the motorcycle, T.J. bounced along the ground, tearing several layers of skin off his arms.

The major concern for the trauma team was an unstable vertebra in T.J.'s back. Swelling had begun to occur, and they feared comprehension on the spine could result in permanent neurological impairment. A "stat" consult was called with the neurologist on-call. Having examined the patient he said, "This is the perfect candidate for the new drug protocol." The neurologist realized that the trauma team was puzzled by what he was saying. He explained that the hospital's Internal Review Board (IRB) had approved a "heroic drug" protocol. It was intended for use in patients facing life- or health-threatening illness or injury for which there was no known remedy or cure. Assured by the neurologist, the trauma team switched into high gear. In the trauma room, the test article was administered to T.J. Thereafter, the team completed its work and the motorcyclist was admitted for trauma surgery.

T.J. survived his serious injuries. He required multiple operations, including extensive skin grafts to both arms. However, he was paralyzed from the waist down. When he found out that he had received an experimental drug without his consent, he was outraged. He retained a lawyer, who filed a multi-count claim against the hospital, the IRB, the neurologist,t and the ER team. The claims ranged from medical malpractice and corporate liability to lack of informed consent. As the lawyer told a local newspaper, "My client would not be paralyzed today but for the fact that he received an experimental drug. They took advantage of the fact that he was unconscious. They claim it was an emergency, but we have experts ready to testify that the situation was not as bad as they thought. Our experts are ready to point out that the trauma team never completed a routine traumatic injury screening and stabilization. The hospital violated its own rules and regulations. No one checked to see if my client had an advance directive. In fact, he had a copy in his wallet. It was completed six months ago and it specifically states, 'No heroic or experimental measures.' "

What really tipped the scales to litigation was a denial of coverage from T.J.'s health plan. Following several levels of review, the help plan denied any medical expenses stemming from the experimental drug treatment. The health plan reviewers disagreed with the neurologist's assessment that the situation was of such an emergent state that no known treatment could alleviate the vertebral problem. In addition, the denial was based on a provision in the health plan policy that stated

> This policy excludes from coverage any and all medical expenses stemming from the use of experimental drug therapy or treatment that was not previously authorized by the plan.

The patient's attorney has now made noises about reporting the situation to the "feds" as an EMTALA violation. He has hinted, too, that he sees this as a violation of applicable state law dealing with what constitutes an emergency and excusing informed consent. He has also suggested that there was a blatant, wanton, and willful disregard of his client's rights under the state advance directive law.

Does this case sound far-fetched? Could a case occur implicating EMTALA, federal human research regulations, state advance directive laws, and the Patient Self-Determination Act? The answer is that this scenario is not far-fetched. Clinical research regulations promulgated in October 1996 have set the stage for such a scenario. Understanding how these compliance-based laws can clash and give rise to litigation is as important a consideration for compliance officers as it is for hospital counsel and risk management practitioners. Effective communication is central to managing this complex matrix of laws.

The Federal Context for the Problem

The FDA has promulgated a regulation that permits emergency research.[1] Utilizing a provision under federal human research regulations, the Secretary of Health and Human Services issued a waiver or variance from the general rules for informed consent in clinical trials for emergency research.[2]

Designed to follow the basic principles of the "emergency exception" to the rules of consent in the therapeutic context, the FDA regulation and the HHS waiver incorporate similar criteria:

- The existence of a life-threatening situation that necessitates intervention.
- Current treatment modalities are either unproven or unsatisfactory to deal with the situation.
- It is not feasible to secure informed consent due to the medical condition of the potential research subject.
- It is not feasible to secure consent from a person recognized in law as having the authority to make treatment decisions on behalf of the potential research subject.
- Would-be research subjects cannot be identified ahead of time regarding the study.
- Both animal and pre-trial studies indicate that the research has the potential for direct benefit to individual research subjects.
- The risks involved in the study are reasonable in terms of the risks and benefits of standard therapeutic treatment.
- Absent a waiver the clinical trial could not be conducted in a practical way.
- The principal investigator must agree to try to contact a legally authorized representative for the research subject and, if possible, to obtain the authorized representative's consent instead of the clinical trial going forward without such an authorization.
- The IRB must approve the informed consent procedures and documents to be utilized in such cases.
- There must be consultation with representatives of the communities in which the clinical trial is to be performed and from which clinical trial participants will be selected.
- Before the study commences there should be public disclosure in the communities in which the clinical trial will take place regarding anticipated risks and benefits.
- Following the conclusion of the study, there must be a public disclosure to the community about the research and its findings.
- An independent data monitoring committee must be established to oversee the clinical trial.
- If the study is done without the consent of the individual or a legally authorized surrogate, the principal investigator must agree to try to communicate with a member of the research subject's family to determine if he or she objects to the subject being enrolled in the clinical trial.
- The IRB has the responsibility to ensure that there is a process in place to notify the research subject, the legal representative, or family member about the person's participation in the clinical study. The notification should include information about the prerogative of the research subject to withdraw from the research project without concern that making such a decision would result in loss of benefits or incur any penalty.[3]

The Patient Self-Determination Act (PSDA)[4] took effect several years before the emergency research regulation and waiver. The law was enacted to encourage effective communication among patients, their families, and healthcare professionals on advance directives. Interestingly, the law does not require patients to have an advance directive.

Like other Medicare and Medicaid providers, hospitals are obliged to provide written information to patients regarding their right to make health care decisions, provide details about how the health care facility implements this right, and educate both staff and the community about advance directives. Additionally, hospitals must document in the patient's medical record whether he or she has an advance directive. Hospitals are also required to comply with applicable state laws on advance directives.

Since the PSDA is tied to Medicare and Medicaid funding, it is a compliance driven law. This fact is reflected in the Medicare Conditions of Participation[5] and the State Operations Manual Survey Protocol for Hospitals.[6] Surveyors have specific interpretive guidelines and procedures on the subject. Indeed, surveyors are supposed to determine if there is evidence that the hospital is promoting and protecting the patient's prerogative to "formulate" an advance directive.

The Emergency Medical Treatment and Labor Act (EMTALA)[7] is applicable to all hospitals that receive Medicare funding and that offer emergency services. EMTALA covers all patients treated at these hospitals, not just Medicare beneficiaries. Participating hospitals must provide a medical screening examination to those who come to the hospital emergency department and request treatment or an examination for a medical condition. If an emergency medical condition is found, the hospital must provide either necessary stabilizing treatment or transfer to another medical facility.

EMTALA violations can result in hospitals being terminated from participating in the Medicare program. Additionally, violators are subject to civil money penalties (CMPs) of up to $50,000 per violation. There is a private cause of action available to those patients who suffer personal harm as a consequence of improper transfer. Hospitals that are the recipients of patients improperly transferred to them can also seek redress for any financial loss as a result of such violations of EMTALA.

Federal Law in Conflict

Viewing the three laws in context, there are apparent contradictions that impinge on patient rights and informed consent.

The PSDA is designed to give patients the right to formulate in writing their desires regarding treatment when they are incapacitated and cannot participate in the decision-making process. EMTALA requires that hospitals provide to emergency department patients medical screening and medical stabilization for those who have an emergency condition.

Neither the PSDA nor EMTALA sanction emergency research. Indeed, the PSDA provides a framework in which individuals can utilize an advance directive to prevent unwanted participation in clinical research trials. EMTALA speaks to medical "stabilization," not medical research. The emergency research consent regulation and waiver are at odds with these two Medicare, compliance-driven laws that are designed to promote patients' rights.

Resolving the Contradictions

In a maze of regulations, it is not unusual to find federal requirements that contradict one another. Hospitals are left to their own resources to reconcile provisions that seem to be incongruent. Interestingly, the three laws all deal with patients' rights and communication. By emphasizing patients' rights and the importance of communication, a resolution is possible.

1. **Assemble the Key Stakeholders.** All too often the Emergency Department, the IRB, and those responsible for addressing advance directives run on parallel tracks. They do not have the opportunity to see that what they do may be inconsistent with other departments, divisions, or units within the health care organization. By bringing the key stakeholders together and advising them of the potential adverse consequences of the three sets of laws, the stage is set for effective communication to prevent regulatory noncompliance.
2. **Develop Shared Clinical Algorithms.** By flowcharting the steps needed for regulatory compliance with each set of laws, leaders can identify conflicts, and decision points that can obviate potential violations of the rules. For example, in the case study, the Emergency Department staff did not complete the EMTALA screening process. On a shared algorithm, they would know about an emergency research protocol, the steps to follow for "rule in or rule out" in terms of advance directives, and the sequence that should be followed with respect to EMTALA. If there were any concerns, the algorithm would include an IRB or clinical research office contact person with whom the ED director could communicate. The same algorithm would pinpoint when to communicate with the hospital compliance officer, risk management practitioner, and legal counsel. It would anticipate post-research follow-up care and support of health plans for such important clinical trials. Instead of working from a set of assumptions, a communications based algorithm would help guide care givers to appropriate choices and away from regulatory noncompliance.
3. **Education Is Essential.** To achieve a firm understanding of how to use the clinical algorithm, key stakeholders need education. Training is important for those who serve on the IRB, in the clinical research office, the Emergency Department, regulatory compliance, the legal counsel and risk management department.
4. **Field Test the Clinical Algorithm.** To be certain that the decision-making process is effective, field tests are in order. Mock cases will help validate the system to make certain that key criteria are met and that communication is efficient and effective when questionable cases are identified in emergency research. If there are parts of the process that do not work, system redesign can be accomplished before the clinical algorithm takes effect.
5. **Address Process Variation.** The goal of the clinical algorithm should be to support patients' rights and quality care. Monitoring for compliance is important to foster such laudable goals and to maintain regulatory compliance. If noncompliance is identified, the system should respond to rectify it immediately.

Conclusion

T.J. would certainly have a firm basis on which to pursue his various legal claims. In the future, however, hospitals can implement processes to avoid regulatory confusion that can give rise to litigation. Effective communication, respect for patient's rights, and a thoughtful approach to the consent process are imperative. Emergency research is important as it holds the key to treatments that can make the difference between permanent disability and recovery following a traumatic event. By involving the right stakeholders in the process, hospitals can overcome regulatory hurdles and foster a culture that supports such research activities. ■

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[1] 21 CFR Parts 5056, 312, 314, 601, 812, and 814.

[2] 45 CFR Section 46.101(i).

[3] See references 1 and 2, supra.

[4] The Patient Self-Determination Act was incorporated in the Omnibus Reconciliation Act of 1990.

[5] See, 42 CFR §482.13(b)(3) (2003).

[6] State Operations Manual, Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (Rev. 1, 05-21-04).

[7] 42 USC Sec. 1395dd (1996), 42 CFR §489.24 (2003).

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compliance programs that the majority of health care providers have enacted. The 7 elements, which are the minimum standards for an effective compliance program, may be summarized as follows:

1. Compliance standards and procedures that are reasonably capable of reducing the prospect of wrongdoing must be enacted.
2. Specific high-level individuals in the organization must oversee compliance.
3. Discretionary authority must be delegated carefully.
4. Compliance standards and procedures must be communicated throughout the organization.
5. Steps must be taken to achieve compliance through monitoring and auditing, and by having and publicizing a reporting system that prevents fear of retribution.
6. Compliance standards must be consistently enforced through appropriate disciplinary mechanisms.
7. The organization must respond appropriately to wrongdoing and endeavor to prevent similar conduct, which may include modifications to the compliance program.

An organization may also mitigate a sentence significantly by self-reporting, cooperation, and acceptance of responsibility. The OIG has clearly adopted that approach in its Provider Self-Disclosure Protocol and in public statements. An organization's sentence can be harsher, however, in cases where:

- High-level personnel participated in or condoned the wrongdoing.
- The organization had a recent prior history of similar misconduct.
- The organization willfully obstructed or attempted to obstruct justice during the investigation, prosecution, or sentencing stages.

It is therefore important to conduct internal compliance processes, including investigations, in a manner that will withstand scrutiny if government regulators or prosecutors get involved.

Recent changes. The Sarbanes-Oxley Act of 2002 mandated increased penalties for several fraud offenses and criminal conspiracy. Through Emergency Amendments in January 2003 and Amendments effective in April and November 2003, the USSC increased Sentencing Guideline levels for such offenses. There have also been enhancements to the Organizational Sentencing Guideline levels in connection with multi-victim crimes, securities offenses, and obstruction-related crimes.

The PROTECT Act, which was passed in April 2003 and relates primarily to the protection of children, mandated that the USSC limit the availability of downward departures, which allow Federal Judges to diminish sentences determined under the Organizational Sentencing Guidelines. In response, in October 2003, the USSC created amendments that prohibited and otherwise limited such departures in a wide variety of cases. These departures were some of the only means by which white-collar defendants could mitigate sentences. The PROTECT Act also changed appellate review of downward departure issues such that federal judges will likely become more stringent in granting diminished sentences.

Advisory Group proposed changes. The Ad Hoc Advisory Group on the Organizational Sentencing Guidelines (the "Advisory Group") was commissioned by the USSC in September 2001, with the mandate that it analyze the Organizational Sentencing Guidelines. Note that this was before the enactment of the Sarbanes-Oxley Act in July 2002. Section 805(a)(2)(5) of the Act directed the USSC to review and amend the Sentencing Guidelines to ensure that they were "sufficient to deter and punish organizational criminal misconduct." The USSC asked the Advisory Group, which was comprised of 15 professionals from many disciplines, to "place particular emphasis on examining the criteria for an effective program to ensure an organization's compliance with the law."

The Advisory Group issued a Report on October 7, 2003, in which it recommended substantial changes to the Organizational Sentencing Guidelines. The USSC adopted the Advisory Group's report and formally proposed to amend the Organizational Sentencing Guidelines on December 30, 2003. On November 1, 2004, the USSC issued the amended Sentencing Guidelines.

First, the Advisory Group noted that in spite of compliance programs, it has recently become obvious that substantial corporate wrongdoing by high-level actors at large publicly held organizations went undetected. This caused the Advisory Group to evaluate whether the Organizational Sentencing Guidelines could be made more effective in preventing and detecting legal violations. It concluded that the Organizational Sentencing Guidelines should better address the role of organizational leadership in ensuring that compliance programs are valued, supported, periodically re-evaluated, and operated for their intended purposes. The Advisory Group also acknowledged that it was influenced by recent Congressional emphasis on organizational culture, improved internal reporting, adequate training, auditing and monitoring, and periodic risk assessments.

Second, the Advisory Group observed that much has changed in the field of organizational compliance since the Organizational Sentencing Guidelines were enacted in November 1991. Over those twelve years, legal standards have recognized organizational compliance programs as important features of responsible conduct. The Advisory Group believed that the Organizational Sentencing Guidelines should be updated to reflect those developments.

The Advisory Group's main recommendation was to turn the 7 elements into a separate sentencing guideline. This proposed guideline expands the importance and meaning of the 7 elements. Again, since the 7 elements are the underpinning of the OIG's Compliance Guidances and, therefore, of most health care providers' compliance programs, wise providers should review this proposed guideline to understand current viewpoints about them. They should then adjust their compliance programs and workplans appropriately to assimilate this current thinking.

Sentencing Guidelines (cont.)

The Advisory Group recommended that the USSC make the following kinds of modifications to the Organizational Sentencing Guidelines:

- Emphasize the importance of an organizational culture that encourages a commitment to compliance with the law.
- Provide a definition of "compliance standards and procedures" referenced in the Organizational Sentencing Guidelines.
- Emphasize the importance of adequate resources and authority for individuals who are responsible for the effectiveness of the compliance program.
- Define the nature of an organization's efforts to determine when an individual in an organization has a reason to know, or history of engaging in, violations of law.
- Include training and the dissemination of training materials and information within the definition of an "effective program."
- Add "periodic evaluation of the effectiveness of a program" to the requirement for monitoring and auditing systems.
- Require a mechanism for anonymous reporting.
- Include an incentive for organizations to seek guidance about potential or actual violations of law.
- Provide for ongoing risk assessments as part of the implementation of an effective compliance program.

Another significant aspect of the Advisory Group's report is that it acknowledged, but did not definitively resolve, the reality that the government may ask for the waiver of attorney-client privilege or attorney work product protections as part of an organization's cooperation with the government. This same concept is raised in the OIG's Provider Self-Disclosure Protocol and the Department of Justice's policies for prosecution of organizations. Providers that are engaging in internal investigations or responding to government inquiries should be more vigilant than ever in addressing, planning for, establishing, and considering the prospect of waiving privileges before beginning the compliance process.

The Advisory Group also discussed the "litigation dilemma," which may be loosely translated as "no good deed goes unpunished." The dilemma is that organizations can be prejudiced because of their good compliance efforts. For example, they can be pressured to waive privileges or protections from discovery, or to turn over internal, self-critical reports aimed at improving compliance. Any voluntary disclosures to the government could then be freely available to hostile third-party litigants. They may also feel pressure to curtail otherwise normal, healthy compliance functions in the following kinds of ways:

- Hedging against promises of confidentiality that are critical to receiving good information in an internal investigation.
- Not fully documenting compliance committee activities.
- Not maintaining initial scores of employees tested on compliance issues.
- Not sharing the results of audits, investigations, and compliance activities within the organization for fear that they could be disseminated to adversaries or turn employees into whistleblowers.

In short, the reality is that self-imposed and self-critical compliance activities such as auditing, monitoring, and self-reporting can create substantial risks for health care providers which have the counterproductive effect (from a compliance standpoint) of diminishing the use of such processes. This dilemma often creates tension among management, counsel, and compliance professionals.

What should providers do? The amended Organizational Sentencing Guidelines, which have been enacted, represent current viewpoints on compliance from a broad array of perspectives. The Amended Guidelines became effective on November 1, 2004. Moreover, the Organizational Sentencing Guidelines are the foundation for most providers' compliance efforts. Health care providers and their counsel should, therefore:

- Read the Advisory Group's report.
- Review organizational policies and procedures to ensure compliance with the current 7 elements and the proposed modifications and clarifications to them.
- Note the areas of emphasis in the Advisory Group's report, and develop or refine organizational policies and procedures to address them.
- Before initiating any internal investigation or responding to any government inquiry, address issues relating to establishing, maintaining, and the potential for waiving applicable privileges.
- Inform senior management and the members of your organization's governing body about the developments and concepts discussed herein. Seek their initial, continued, or increased support and involvement for your compliance efforts. ■

Adapted from The Health Care Compliance Professional's Manual.