HIPAA

Time for a Health Care Corporate Compliance Program

By Philip H. Hilder and Lon Mullen

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) has enjoyed regular press coverage since it became law on Aug. 21, 1996. Regulators, insurers, program suppliers, and providers are attempting to come into compliance with its portability provisions, which will benefit employees seeking health insurance continuity incident to a job change, assure mental health benefits, and require that insurers sell to small employers with two to 50 employees.

The act also strengthens the authority for health care fraud and abuse investigations by expanding funding for the Office of the Inspector General (OIG) within the U.S. Department of Health and Human Services (DHHS) and for the FBI to initiate and coordinate federal and state civil and criminal investigations of activities incident to Medicare, Medicaid, other public, and even some private programs. The act empowers Medicare intermediaries and carriers to ferret out potential fraud and abuse and increases the incentives for whistleblowers to report their allegations/suspicions to the government. Every new legislative/budget cycle includes additional funding for fraud and abuse investigations or new sanctions for violations of existing fraud and abuse rules. The recently enacted Balanced Budget Act (PL 105-33) presents vivid examples of legislative attention to fraud and abuse, including a new civil monetary penalty for violations of the Medicare and Medicaid anti-kickback law with treble damages plus a penalty of $50,000 per violation. A health care organization places its assets in jeopardy unless it has made a well-informed decision regarding its self policing of compliance with the law. The intensified attention to fraud and abuse is paralleled by the emergence of the "qui tam" right of private action in which persons can file sealed "false claims" lawsuits and ultimately share with the government in any recovery.

This article describes the context for this intensified attention, the provisions of HIPAA with implementing regulations or guidelines, and the implications for participants in the health care system and their lawyers. Any legal representation and any legal advice requires thorough preparation regarding the content of the act and the potential punishment for violations. The health care system is being watched under a scanning bright light, and should that light fall upon the unwary, the consequences could be crippling or even fatal to an enterprise. The enormous amounts of money coursing through public programs, employer-sponsored programs, and private com-

mercial insurance justifies the investment in monitoring and enforcement. The time has passed, if indeed it ever existed, when the response to detection of an aggressive billing tactic was at most a disallowance or an adjustment. Attorneys now must advise their clients about the parameters of the law before contracts are entered into or billing begins; about if, when and how to undertake internal fraud audits and to establish corporate compliance programs; what and when to disclose to the government or other payors; as well as defend those accused of violations. The emphasis must be on prevention because mere allegations and/or investigations, even without filed charges, can ruin a health care provider or supplier. The government agencies talk about prevention and voluntary compliance, but their major incentive for compliance is aggressive enforcement, so it is up to the provider to adopt a sufficiently vigorous compliance program to avoid the ire of the OIG, the Department of Justice and their state counterparts.

The Health Insurance Portability and Accountability Act (HIPAA) gives authorities a new weapon that creates additional accountability which shifts attention to compliance issues that have a prophylactic effect against fraud and abuse.

Prior to HIPAA, healthcare providers were regulated under the following:

1. Federal and state anti-kickback statutes;
2. Federal prohibition on "self-referral" of Medicare and Medicaid patients: "Stark I and Stark II";
3. Civil monetary penalties law;
4. State commercial bribery and corporate practice of medicine statutes;
5. False Claims Act (1986); and
6. U.S. Sentencing Commission "guidelines for organizations (1992)."

Also part of the regulatory context is Operation Restore Trust which is an interagency task force charged with developing methods for investigating fraud and abuse. It began in five states (Texas, California, Florida, New York and Illinois) and is expanding into additional states.

On Aug. 14, 1997, the U.S. Department of Justice reported that the number of FBI health-care fraud investigations rose to 2,200 in fiscal year 1996 from 657 in fiscal 1992. Federal prosecutions increased to 246 cases and 450 defendants from 83 cases and 116 defendants, and convictions rose to 307 from 90 for this same time frame. Meanwhile, civil health care fraud investigations by the Justice Department soared to 2,488 in 1996 from 270 in 1992.[1] The Department of Justice is conditioning every settlement upon implementation of a corporate compliance program.

It is not only federal investigators pursuing health care providers, whistleblowers from within the system are now routine participants in the investigative process. Recently, Dr. Jim Montagano, a surgeon, initiated a false claims lawsuit in which the United States intervened. This lawsuit resulted in a settlement payment of $12.6 million by four Ornda Health Corp. hospitals in California. The surgeon claimed that hospital contracts with doctors recited nonexistent duties in unjustified directorships to disguise payments to the doctors for patient referrals. The lawsuit asserted that these kickbacks violated the Medicare anti-kickback and Stark physician self-referral laws, and that false claims arose each time Medicare was billed for a service provided to a patient referred by a doctor who had an improper financial arrangement.

Columbia/HCA Healthcare Corp. has reacted to a well-publicized federal investigation by changing its leadership and the way it conducts its business. Columbia/HCA has accomplished this change by increasing its reviews of Medicare coding; establishing stronger guidelines for transactions with physicians; discontinuing sales of an ownership interest in hospitals to physicians and unwinding existing physicians' ownership interests; eliminating annual cash incentive compensation for company employees; and hiring an executive vice president to serve as in-house compliance officer reporting directly to the CEO. Columbia/HCA has committed, among other things, to developing a compliance plan for the company's laboratory billing procedures.

When confronted with allegations of wrongdoing, other providers have agreed to undertake corporate compliance programs as a condition of reduced penalties. The HHS Inspector General's Office announced on Aug. 7, 1997, that it was in the final stages of developing and issuing a model compliance plan for hospitals. The plan designed "to help hospitals become good corporate citizens and better abide by the rules and regulations of doing business with the government."[2] During the fall of 1997, the OIG reworked the model Hospital Compliance Plan in response to extensive feedback from the hospital industry. A final plan was circulated through the American Hospital Association on Jan. 23, 1998. According to news reports, it is probable that Columbia/HCA will commit to compliance with such a model plan. Others will also commit to such a model plan if the plan is classified in honoring its voluntary nature, distinguishing it from the more punitive remedial plans exacted in the settlement of enforcement actions.

HIPAA's fraud and abuse provisions highlight the intensified interest in enforcement. These include:

1. Expansion of the Medicare and Medicaid anti-kickback statutes to other federal health care programs;
2. Coordinated fraud and abuse program designed to deter, detect, and punish fraud and abuse by con-

ducting investigations, facilitating enforcement, establishing a national data bank to receive and report final adverse actions against health care providers, and guidance to industry through mandating advisory opinions; (the mandate for the OIG to issue advisory opinions on whether a proposed health care business violates the federal anti-kickback statute was expanded to include analysis for any violations of the Stark self-referral prohibition by the Balanced Budget Act);
3. Fraud and abuse control account including significant and increasing appropriations *and* the dedicated deposit of all recoveries from the anti-fraud and abuse activities;
4. Increased civil money penalties; and
5. Expanded sanctions applicable to health care fraud.

At the same time, the law provides some relief for participants in the provision of health care services beyond the mandatory issuance of advisory opinions. These include:

1. Tightening of the intent standard for imposition of civil money penalties to "knowingly presents a claim that the person knows or should know is prohibited," (the administration proposed that this higher burden of proof be repealed, but was rebuffed when Congress opted not to repeal this provision in the Balanced Budget Act);
2. Excepting from the anti-kickback statute risk sharing arrangements; and
3. Establishment of (and modification of) safe harbors when appropriate.

I. Regulatory Context

The context surrounding these changes is one of vigilance, suspicion, and even some hostility. The anti-kickback statutes penalize anyone who knowingly and willfully solicits, receives, offers or pays remuneration in cash or in kind to induce or in return for: (a) referring an individual to a person for the furnishing or arranging for the furnishing of any item or service payable under the Medicare or Medicaid program, or (b) purchasing, leasing or ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item payable under the Medicare or Medicaid program.[3] Most states have parallel prohibitions pertinent to the Medicaid program and other third-party payers. These are criminal statutes, which require a showing of criminal intent. Since 1987, the Secretary of HHS must issue regulations specifying those payment practices which will not be subject to criminal prosecutions under the anti-kickback statute and will not provide a basis for program exclusion. When issued, such regulations constitute "safe harbors."

The Stark law prohibits a physician who has a financial relationship with an entity from referring Medicare patients to the entity for the furnishing of an extensive list of services and also prohibits the entity from billing Medicare for such services. There is a limited set of specific exceptions; however, unless such an exception exists, the prohibitions are self-enforcing with no intent or knowledge necessary for enforcement. The penalties include denial of payment, refunds, exclusion from programs, and a cash money penalty of up to $15,000 for each service (or up to $100,000 for participation in circumvention schemes), and a civil money penalty of up to $10,000 for failure to meet reporting requirements.[4]

Civil monetary penalty laws control practices without any requisite showing of criminal intent. Other state statutes, include commercial bribery and corporate practice of medicine laws. For example, the Texas Commercial Bribery Statute invokes the fiduciary obligation of a physician to his/her patient and the attendant prohibition on accepting any payment or arrangement which could interfere with that obligation. The corporate practice of medicine prohibition prohibits corporations from securing the services of physicians by employment or similar arrangements and offering the physician services to the public. This doctrine is relevant to the anti-kickback statutes, which exempt arrangements with employees.

The False Claims Act of 1986 supports whistleblower ("qui tam") actions and can result in both penalties and treble damages, with whistleblowers retaining a portion of the proceeds recovered.

U.S. Sentencing Commission "Guidelines for Organizations (1992)" can invoke corporate probation or a corporate "death penalty," with penalties calibrated under a "culpability index."

II. HIPAA

HIPAA expands the criminal law of fraud beyond mail fraud and well beyond Medicare and Medicaid.

Section 241. Definitions Relating to Federal Health Care Offense. Defines "federal; health care offense" to include violations of, or criminal conspiracies to violate, specific provisions of the U.S. Code if the violation or conspiracy relates to a "health care benefit program." The act defines "health care benefit program" broadly to include:

> Any *public or private* plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.

However, health care fraud is defined to include intent. It requires that an individual knowingly and willfully execute, or attempt to execute, a scheme or artifice —

1. To defraud any health care benefit program; or
2. To obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program.

Violations may result in fines or imprisonment for not

more than 10 years, or both. If the violation results in serious bodily injury, the maximum jail term is 20 years. If the violation results in death, the maximum jail sentence is life imprisonment.

The act creates a criminal sanction for "knowingly and willfully" embezzling, stealing, or otherwise without authority converting any of the monies, property, or assets of a health care benefit program.

The act similarly creates a criminal penalty for an individual or entity who "knowingly and willfully":

- Falsifies, conceals or covers up by any check, scheme, or device or material fact; or
- Makes any materially false, fictitious, or fraudulent statements or representations,

in connection with the delivery of, or payment for, health care benefits, items or services.

Willful obstruction of Criminal Investigations of Health Care Offenses also creates criminal liability. An individual who *"willfully"* prevents, obstructs, misleads, delays, or attempts to prevent, obstruct, mislead, or delay, the communication of information or records relating to a violation of the federal health care offense to a criminal investigator is subject to fines or imprisonment for not more than five years, or both.

The act expands the federal money laundering statute to "any act or activity constituting an offense involving a Federal health care offense."

It also authorizes injunctive relief in situations where an individual or entity is "committing or about to commit a Federal health care offense." Further, the act authorizes the freezing of assets in similar situations.

The act aids investigators, by authorizing the attorney general or a designee to obtain a subpoena requiring the production of records relevant to a health care investigation or requiring a custodian of records to give testimony concerning the production and authentication of such records. The section restricts the use of certain health information gathered pursuant to this section and provides immunity from civil liability for individuals receiving a subpoena under the section who comply in good faith with the subpoena.

Finally, the act provides that a court "in imposing sentence on a person convicted of a Federal health care offense, shall order the person to forfeit property, real or personal, that constitutes or derived, directly or indirectly, from gross proceeds traceable to the commission of the offense." Property forfeited under this section is to be deposited in the Federal Hospital Insurance Trust Fund.

III. Implications of HIPAA

Prosecutors can utilize a federal enforcement system with 400 full-time F.B.I. agents, compared to 50 in 1991 and over 100 prosecutors dedicated to preventing and/or punishing health care fraud. Similarly, there were 178 new qui tam cases in 1996 alone, and a continued surge in whistleblower activity in 1997 and 1998. Cases involving systematic intentional denial of necessary care or provision of an inadequate quality of care are being prosecuted as fraud. HIPAA's beneficiary incentive program rewards individuals who report violations of fraud and abuse laws or who suggest ways to improve the efficiency of Medicare.

The message is clear that a provider must make every effort to ensure that his or her program is vigilant regarding the propriety of its practices. One approach is to undertake a corporate compliance plan. Such a plan would significantly improve an entity's negotiating position with federal authorities, as well as provide some relief under the federal sentencing guidelines, if needed. On the occasion of releasing a model compliance plan for clinical laboratories, Attorney General Reno said: "To medical laboratories who ignore this advice, our warning is clear: we will bring the full weight of the federal government's powers to bear to enforce the law and protect the American people from being ripped off."[5]

That model compliance plan suggests 11 "action" elements. These include:

1. Written standards of conduct for employees.;
2. Written policies that promote a commitment to compliance and address areas of potential fraud;
3. Designating a chief compliance officer or an equivalent committee;
4. Education and training of all employees;
5. Audits and implementing other techniques to monitor compliance and reduce problems;
6. Developing a code of improper/illegal activities and disciplining employees who violate internal compliance policies or laws;
7. Making promotion of and adherence to compliance a factor in evaluating supervisors and managers;
8. Investigating and remediating systemic and personnel problems;
9. Prohibiting the employment or retention of anyone sanctioned for health care offenses;
10. Maintaining a hotline for complaints and adopting procedures to protect anonymity; and
11. Adopting record creation and retention requirements.

This model has been roundly criticized, as indeed has the very concept of a compliance program — too expensive, too risky, and too diversionary from the mission of delivering quality health care. The risk of finding something "wrong" and being required to report it and correct the system which produced it is very real, but is must be weighed against the language in HIPAA, which calls for a higher level of personal responsibility for executives or board members who either knew, or *should have* known, of conditions allowing the occurrence of fraudulent or abusive practices. This concern is exacerbated in the latest draft of the hospital compliance plan which states that "the elements proposed by this model parallel those of the clinical laboratory model compliance plan ... and our corporate in-

tegrity agreements."

Stepping back for perspective it is clear that any compliance review should provide answers to the following questions:

1. Does the arrangement involve only patients not covered by Medicare, Medicaid, or other federal government programs? If the answer is yes, are there any spillover effects?
2. Does the state, whose laws control the transaction, prohibit the corporate practice of medicine? If so, is the contemplated relationship consistent with the prohibition or can it be restructured to be consistent?
3. Does the entity have a "financial relationship" with any referring physicians? If so, does the entity provide any "designated health services" to any patients referred/admitted by a physician with a financial relationship? Does the proposed relationship then come within the general coverage of the Stark law? Does it satisfy any of the Stark exceptions?
4. Will remuneration be offered, paid, solicited, or received with an intent to influence the judgment of a person in the referral, recommendation, or arranging for services incident to a covered program? Even if the answer is no, is there a significant possibility that circumstances would allow an inference of such intended action? Does the arrangement meet all of the requirements of an exception or of a "safe harbor"?
5. Does the state law include anti-kickback, self-referral, commercial bribery or other applicable laws with different requirements than the federal laws? If so, does an analysis under state law indicate compliance with state law?
6. For tax exempt entities, does the arrangement result in total compensation to the physician which exceeds "reasonable compensation," or has it features which could be considered "private benefit" or "private inurement"? Does it involve "private use" of facilities financed with outstanding tax exempt debt, or does it comply with "safe harbor" requirements of tax law contained in Rev. Proc. 93-19?

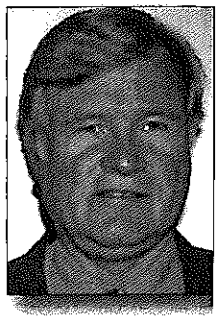
The dedication of the federal government, state government, and various third-party payers to deter, detect and punish instances of health care fraud and abuse must be taken very seriously. Indeed, even though the HCFA Administrator Designate Nancy Ann DeParle testified before the Senate Finance Committee on Sept. 10, 1997, that her top priorities would be implementing the Balanced Budget Act of 1997 and more aggressively fighting fraud and abuse in Medicare, Senator Tom Harken (D-Iowa) announced on Oct. 3 that he will put a hold on her nomination until there is a firm commitment to making the fight against Medicare fraud and abuse "top priority." The confirmation did occur somewhat short of such a guarantee, but the administrator did assure the senator that fraud and abuse was a top priority of HCFA.

Every entity must examine its own practices and make a judgment based upon legal, ethical, and business principles, including a recognition that its actions are subject to strict scrutiny. The existence of a corporate compliance program may be a significant advantage if criminal sentencing guidelines ever become a factor, and also to avoid investigation and conviction. An informed compliance program may well be the option of choice in an atmosphere where merely "not knowing" will not suffice as a defense. The requisite due diligence implicates the corporate culture, which must be consistent with, and supportive of, compliance. Incentive goals which can only be met by noncompliance or are likely to precipitate or encourage noncompliance must be eliminated and income projections meant to inform the capital markets must be computed based upon compliance with the law.

It is the responsibility of the attorney to apprise his/her client of the context described in this article and to tender advice consistent with the law and the current enforcement atmosphere. That context is one in which government scrutiny will continue to intensify and mistrust will accelerate with each new indictment. ■

Philip H. Hilder formerly was the attorney-in-charge of the Houston Field Office of the U.S. Department of Justice, Organized Crime Strike Force, and was an assistant U.S. attorney for the Southern District of Texas. He practices in the area of white-collar criminal defense and related litigation in Houston, Texas. In 1995, he was elected president of the Federal Bar Association, Houston Chapter, and is a member of the ABA subcommittee on Healthcare Fraud and Abuse.

Lon Mullen began specializing in health law in 1974, becoming the deputy director for the national Health Law Program at U.C.L.A. He then went on to become senior program officer, attorney advisor, and acting deputy for the U.S. Department of Health and Human Services, Office of Planning and Evaluation in Washington D.C. Since leaving government service in 1982, he has been in the private practice of health care law and is with the Houston, Texas, law firm of Broocks, Baker & Lange, L.L.P.



Endnotes

[1]WALL STREET JOURNAL, Aug. 14, 1997, at A4.

[2]HEALTH CARE DAILY REPORT, BNA, Aug. 8, 1997, at 8.

[3]42 U.S.C., Section 1320 a-7b(b)

[4]42 U.S.C. 1395 nn.

[5]HEALTH LAWYERS NEWS, April 1997, Vol. 1 No. 4, at 1.