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Government and Internal Investigations

Special Issues for Healthcare Providers

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The successive waves of publicity accompanying the various crises in our economy are inevitably accompanied by new legislation and renewed government scrutiny and regulatory enforcement. Thus, the savings and loan and corporate governance scandals produced a wave of government investigations and criminal prosecutions. In recent years, the healthcare industry also has come under increasing government scrutiny.

Many of the techniques for responding to government investigations of complex organizations and conducting internal investigations apply with equal force in the healthcare context as in any other industry. Thus, for example, taking care to advise an employee that one represents only the employer (the so-called *Upjohn* warning)[1] when conducting an interview during an internal investigation, is no different if one's client is a nonprofit hospital or a for-profit corporation. Similarly, the need to conduct an internal investigation with the awareness that attorney work product materials, if disclosed to a government agency, are likely to find their way into the hands of private litigants, is a concern shared equally by healthcare entities and other businesses subject to a government investigation.

By their nature, however, healthcare entities face unique problems when responding to government investigations or conducting an internal investigation in response to an allegation of improper conduct. An awareness of the special aspects of the healthcare industry is essential. Some of these unique aspects include: 1) when to report misconduct of a healthcare institution; 2) the special confidentiality requirements of healthcare records; 3) the importance of medical staff bylaws; and 4) intent defenses to criminal charges in the healthcare area.

Reporting of Misconduct

As a general rule, many advantages can be gained by cooperating with a government investigation or voluntarily reporting misconduct. For example, the Antitrust Division of the Department of Justice has a formal amnesty program for those companies that first bring an antitrust violation to the division's attention.[2] Similarly, the False Claims Act[3] provides reduced financial penalties for those entities making voluntary, early

self-disclosure of problematic claims. Most importantly, the so-called Thompson memorandum, which governs Department of Justice prosecutions of business organizations, includes the "timely and voluntary disclosure of wrongdoing" as a crucial factor in determining whether to charge a corporation with a crime, and the sentencing guidelines for organizations reduce fines for companies that submit a voluntary disclosure.[4]

While the decision whether and to whom to disclose must be driven by the facts of the particular case, the general principle that early and voluntary self-reporting of misconduct may confer a valuable benefit applies with equal force to healthcare entities. Several formal avenues exist, including, for example, the self-disclosure protocol set forth by the Office of Inspector General, Department of Health and Human Services.[5] For healthcare entities, however, other aspects of reporting misconduct must be considered.

For a healthcare entity, the reporting of misconduct, either of the institution or its employees, may not be discretionary. At the federal level, a healthcare entity that "takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days" must report the disciplinary action to the National Practitioner Data Bank and New Jersey State Board of Medical Examiners.[6] As set forth in the *National Practitioner Data Bank Guidebook*,[7] it is not the investigation that is reported but the restriction of clinical privileges.

This area of reporting can become complex, because neither the statute nor case law makes clear what constitutes a "professional review action," or when an action "adversely affects clinical privileges." The *National Practitioner Data Bank Guidebook* further complicates the issue by suggesting that doctors in an employer/employee relationship with a hospital may be fired pursuant to an "Alternative Employment Termination Procedure" that does not constitute a "professional review action," and is therefore not reportable. For licensed healthcare professionals who are not physicians, reporting of disciplinary actions by healthcare entities is discretionary.[8]

The state of New Jersey has its own reporting obligations set forth in the Health Care Professional Responsibility and Reporting Enhancement Act.[9] The New Jersey statute is broader than its federal counterpart, requiring written notification to the Division of Consumer Affairs[10] when a healthcare professional employed by or under contract to provide services to a healthcare entity "has conditions or limitations placed on the exercise of clinical privileges or practice within the health care entity for reasons relating to...incompetency or professional misconduct...."[11] Like the federal statute, New Jersey requires the reporting of the action taken against the healthcare professional, not the investigation itself.

An entire article could be written about the nuances of reporting obligations for healthcare providers. For example, nursing homes or long-term care facilities have specialized reporting obligations. When conducting an internal investigation involving a healthcare entity or responding to a government investigation, counsel must, at a minimum, be keenly aware that corrective actions taken may have to be reported to regulatory authorities.

Healthcare institutions may be reluctant to take aggressive steps to address misconduct because of the resulting reporting obligations. Counsel's job often becomes not only gathering the facts to respond to a government query or allegation of misconduct, but assisting the healthcare entity in shaping its response to those facts in light of its reporting obligations.

Confidentiality of Records

Confidentiality should be a paramount concern for a healthcare provider during either an internal or government investigation. The most expansive source of privacy obligations for healthcare providers is the Health Insurance Portability and Accountability Act (HIPAA).[12] HIPAA generally prohibits healthcare providers from disclosing "protected health information" (PHI), such as information about an individual's physical or mental health or condition and the provision of healthcare to an individual. HIPAA is implicated during both internal and government investigations of healthcare providers.

During an internal investigation, counsel is entitled to access PHI without patient consent or authorization. Federal law specifically states that a healthcare provider "may use or disclose PHI for its own treatment, payment, or healthcare operations."[13] The term "healthcare operations" includes "[c]onducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs."[14]

Nonetheless, counsel may be faced with healthcare employees who—either in an effort to interfere with an internal investigation or out of a sincere but misinformed understanding of the law—refuse to disclose information to counsel in reliance on HIPAA. Counsel should be prepared to confront this objection, explain why HIPAA is inapplicable, and deal appropriately with employees who continue to resist the investigation.

During a government investigation, a healthcare provider must produce PHI when ordered by a court to do so.[15] Dis-

closure of PHI is also mandatory when compliance with the confidentiality requirements is the subject matter of an investigation by the Department of Health and Human Services. Indeed, withholding PHI under these circumstances *violates* HIPAA.[16]

On the other hand, a healthcare provider *may* release the information when a "health oversight agency" is seeking PHI for "oversight activities," including "civil, administrative, or criminal investigations."[17] A health oversight agency is a federal or state agency "authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant."[18] The Department of Justice is a health oversight agency.[19]

Subject to certain exceptions,[20] a healthcare provider is usually permitted to disclose PHI to government investigators. In civil litigation, however, the health oversight agency exception is typically inapplicable and, unaccompanied by a court order, a subpoena does not, by itself, relieve a healthcare provider of its obligation to maintain the confidentiality of PHI. Particularly when civil litigation follows criminal proceedings—as is often the case—healthcare providers must not make the mistake of disclosing PHI to civil litigants under the misimpression that it is no longer protected because it was already disclosed to the government.

Upon receiving a subpoena or other request from government investigators, the best approach is to first determine whether PHI is being sought. If it is, then the second issue to address is whether compliance with confidentiality requirements is the subject matter of the investigation. If so, the information must be disclosed. If not, then the third step is to determine whether the information may be disclosed under the health oversight agency exception to HIPAA.

In addition to HIPAA (and state laws governing the confidentiality of patient information), healthcare providers must be aware of other laws that could be implicated by internal or government investigations. For example, the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992, though covering a narrower scope of patient records (mainly substance abuse treatment records), imposes even stricter confidentiality requirements than HIPAA. As a general proposition, records falling within the purview of this act should only be disclosed pursuant to court order.[21]

In the healthcare field, confidentiality requirements also exist outside of the context of patient records. For instance, New Jersey regulations expressly require hospitals to keep personnel records confidential, and to limit access "to authorized personnel who have clearly established their identity."[22]

Overall, statutes and regulations restricting the disclosure of information and records are ubiquitous in the healthcare field. Special care must be paid during both internal and government investigations to ensure that a healthcare provider does not run afoul of these obligations.

The Role of Medical Staff Bylaws

Another complicating factor for healthcare entities responding to government investigations or conducting an internal investigation in response to an allegation of misconduct is the presence of medical staff bylaws. For many hospitals and other healthcare institutions, the vast majority of the professional medical personnel are not salaried employees, but rather independent physicians, dentists and other professionals who are members of the institution's medical staff, granted privileges to admit patients or practice medicine at the institution via its medical staff bylaws.[23]

The maintenance of privileges in good standing at area hospitals is critical for physicians to practice medicine. For this reason, medical staff bylaws often contain an array of due process protections for physicians accused of misconduct. The bylaws typically require that special committees of medical professionals at the institution be appointed to investigate allegations of misconduct accompanied by the right of the accused doctor to present evidence to the committee, have a hearing, and pursue an appeal to hospital management. The details of these arrangements vary widely by institution.

The provisions of medical staff bylaws often present many dilemmas for counsel conducting an internal investigation or assisting with the response to a government query. The first question that typically arises is whether the process set forth in the bylaws should be invoked. If the subject matter of an investigation relates to the conduct of an individual physician, as opposed to the institution itself, the due process provisions of the medical staff bylaws may be invoked.

On the one hand, a healthcare institution is often reluctant to proceed via the investigative/disciplinary procedures set forth in the medical staff bylaws because of the delay, cost, and exposure of information within the institutional community that inevitably follow.[24] On the other hand, not proceeding pursuant to the bylaws may invite the claim that the healthcare entity violated the physician's rights if misconduct is found but later disputed

by the doctor.

Conducting an internal investigation through counsel may provide a way to avoid triggering the due process requirements of the medical staff bylaws and to gain the protections of the attorney-client privilege and work product doctrine. Bylaws often allow institutional committees investigating physician misconduct to delegate some of their responsibilities. Outside counsel can gather information, interview witnesses, and then present their preliminary findings to the appropriate committee under the bylaws for consideration and further action.

Intent Defenses to Criminal Liability

Counsel's role in conducting an internal investigation or responding to a government inquiry will usually involve developing defenses to potential criminal charges. In the healthcare context, prosecutors have been particularly aggressive in alleging fraud or false statements in submissions to Medicare and other federal programs.

The complexity and ambiguity of the regulations and statutes governing healthcare programs often make it difficult for even an experienced healthcare professional to be sure that his or her conduct is correct, or at least that it will not be subject to challenge later. For example, whether a service is covered by Medicare or another federal program or a procedure is properly coded can be a matter of debate. Thus, in the healthcare context, more so than in others, it may be crucial for counsel to determine not only the underlying facts, but also the intent of employees and their belief regarding the legality of their conduct.

All of the criminal statutes under which the federal government ordinarily undertakes healthcare investigations or prosecutions require proof of specific intent. The mail, wire and healthcare fraud statutes[25] require an *intent to defraud*. The various false statement statutes[26] require that the criminal conduct be *willful*. The criminal provision of the False Claims Act[27] requires that the allegedly false claim be made "knowing such claim to be false, fictitious, or fraudulent." Conviction under this statute requires that the defendant acted "with a consciousness that he was either doing something which was wrong, or which violated the law."[28]

Intent to defraud is the intention to deceive by deliberately misstating, omitting or concealing a material fact, and thereby obtaining money or property the defendant would not have obtained had the facts been fully and truthfully disclosed.[29] It follows that a party's "good faith" belief in the truth of its representations is a "complete defense" to fraud offenses such as mail and wire fraud because it negates a specific intent to defraud.[30]

Ordinarily, the good faith in issue in a healthcare case relates to the truth of the provider's representations of fact. When a complex statutory or regulatory scheme is involved and the criminal statute requires proof of specific intent, a defendant's good faith belief that its conduct was lawful may provide an additional defense independent of the truth of its representations.

In *Ratzlaf v. United States*[31] and *Cheek v. United States*,[32] the Supreme Court held that where a statutory scheme is complex, the government must prove that the defendant knew his or her actions were unlawful to prove that he or she acted willfully. The Third Circuit reached a similar result in *United States v. Curran*,[33] which held that the government was required to prove that a defendant knew he or she was violating federal Election Commission regulations in order to convict him or her of willfully making a false statement.

A party's good faith belief in the lawfulness of its conduct negates criminal intent where the law was ambiguous, the party did not make false statements of fact, and the party's interpretation of the law was honestly held in good faith. Thus, in *United States v. Migliaccio*,[34] the defendant was acquitted on charges of submitting fraudulent claims for health services that the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) did not cover. The coverage regulations were ambiguous, there was evidence that the defendants had made their claim based on a reasonable, good faith interpretation of the regulations, and the district court erred by not giving an instruction that good faith belief in their interpretation of the law was a defense.

Knowledge of illegality does not affect criminal intent in those cases where the law is clear and the forbidden nature of the conduct self-evident.[35] But the statutes and regulations governing Medicare and other healthcare programs are often neither clear nor simple. Instead, Medicare is "a complex and highly technical regulatory program."[36] The governing statutes and regulations have been described as "among the most completely impenetrable texts within human experience."[37]

It follows that a defendant's good faith belief in its right to payment under ambiguous healthcare regulations negates intent to defraud or knowledge that a claim is without legal basis:

> Medical and hospital care reimbursement programs are very detailed and complex. In addition, the law is not always clear about what is or is not a reimbursable expense or cost. *The law does not intend that a person or organization be criminally prosecuted for ignorance or good faith mistaken legal judgments regarding what is or is not a reimbursable expense or cost.* There-

> fore, the law requires that a person knowingly violate the law. *"Knowingly" in the context of medical reimbursement means not only that the defendant knows he submitted a claim, but also that the defendant knows the claim is false and that he is not entitled to payment on it.*[38]

Thus, in *United States v. Whiteside*,[39] the defendant was acquitted of making a willfully false statement on a Medicare cost report because the statement categorized an expense in accord with the defendant's good faith interpretation of an ambiguous regulation.

> In a case where the truth or falsity of a statement centers on an interpretive question of law, the government bears the burden of proving beyond a reasonable doubt that the defendant's statement is not true under a reasonable interpretation of the law.[40]

Because the theories underlying healthcare prosecutions have become so aggressive, and the regulatory environment so complex, the knowledge and belief of healthcare practitioners in the legality of their actions is more important than in other contexts. Counsel would be well advised to probe this area during investigation and fact gathering more so than in other contexts.

Conclusion

Government investigations of healthcare providers are on the rise. Although many of the techniques for responding to government investigations of complex organizations and conducting internal investigations are applicable in the healthcare industry, it is essential that healthcare providers and their counsel also understand and are prepared to handle the many unique issues that arise. ⚖

Endnotes

1. *Upjohn v. United States*, 449 U.S. 383, 397 (1981).
2. The Aug. 10, 1993 Department of Justice Corporate Leniency Policy is available at: http://www.usdoj.gov/atr/public/guidelines/lencorp.htm.
3. 31 U.S.C. §§ 3729-3733.
4. *See* Memorandum of Larry D. Thompson, deputy attorney general, Jan. 20, 2003, available at http://www.usdoj.gov/dag/cftf/corporate_guidelines.htm, and *United States Federal Sentencing Guidelines Manual*, Ch. 8.
5. *See* An Open Letter to Health Care Providers, April 24, 2006, Department of Health and Human Services available at http://www.oig.hhs.gov/fraud/openletters.html.
6. 42 U.S.C. § 11133(a)(1)(A).
7. The guidebook is currently undergoing revision by the Department of Health and Human Services; the Sept. 2001 version is the most recent available to the public.
8. 42 U.S.C. § 11133(a)(2).
9. N.J.S.A. 45:1-33, *et seq.*
10. The division's deputy attorneys general are counsel to the Board of Medical Examiners.
11. N.J.S.A. 26:2H-12.2b(a)(2).
12. 42 U.S.C. § 1320d, *et seq.*
13. 45 C.F.R. § 164.506(c)(1).
14. 45 C.F.R. § 164.501.
15. *See* 45 C.F.R. § 164.512(e)(1)(i).
16. 45 C.F.R. §§ 160.310(c), 164.502(a)(2).
17. 45 C.F.R. § 164.512(d)(1).
18. 45 C.F.R. § 164.501.
19. 65 Fed. Reg. 82462, 82492 (Dec. 28, 2000).
20. *See* 45 C.F.R. § 164.512(d)(2).
21. *See* 42 U.S.C. § 290dd-2.
22. N.J.A.C. § 8:43G-5.2(k).
23. New Jersey regulations require hospitals to have institutional bylaws governing medical staff. N.J.A.C. § 8:43G-16.2(a).
24. This is especially so where the medical staff bylaws call for investigative committees to be composed of doctors not in economic competition with the doctor under investigation. The unintended effect of such provisions is to often broaden awareness of the inquiry within the healthcare entity.
25. 18 U.S.C. §§ 1341, 1343 and 1347.
26. 18 U.S.C. §§ 1001, 1035, 42 U.S.C. § 1320a-7b.
27. 18 U.S.C. § 287.
28. *United States v. Bolden*, 325 F.3d 471, 494 (4th Cir. 2003).
29. *See, e.g., United States v. Coyle*, 63 F.3d 1239, 1243 (3d Cir. 1995).
30. *See, e.g., United States v. Khorozian*, 333 F.3d 498, 508 (3d Cir. 2003).
31. 510 U.S. 135 (1994) (money laundering).
32. 498 U.S. 192 (1991) (income tax evasion).
33. 20 F.3d 560, 570 (3d Cir. 1994).
34. 34 F.3d 1517, 1524 (10th Cir. 1994).
35. *See, e.g., United States v. Zehrbach*, 47 F.3d 1252 (3d Cir. 1995) (bankruptcy fraud by bid rigging at auction).
36. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).
37. *Rehabilitation Ass'n v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994).
38. *United States v. NHML, Inc.*, 2000 U.S. App. LEXIS 1389, *10 (6th Cir. 2000) (emphasis added).
39. 285 F.3d 1345 (11th Cir. 2002).
40. *Id.* at 1351.

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