Medicolegal Sidebar

Medicolegal Sidebar: Expanding Hospital Liability—The Concept of Willful Blindness

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Healthcare spending in the United States far exceeds that of other nations such as Australia, United Kingdom, France, and Germany [7]. In fact, US healthcare expenditures in 2015 increased 5.8% over the previous year, to reach USD 3.2 trillion, or close to USD 10,000 per person [1]. The federal government is concerned that healthcare fraud may contribute to higher healthcare costs. Accordingly, federal prosecutors have aggressively targeted

physicians and other healthcare providers who are suspected of fraudulent billing practices, under a statute titled 18 U.S.C. § 1347 [4]. This statute addresses providers who attempt to defraud any healthcare benefit program through false billings or other misrepresentations that are designed to obtain money from the program. If convicted, a defendant charged under § 1347 can face fines and prison. The statute specifies that a guilty party need not have actual knowledge of the relevant law, nor even have a specific intent to commit a violation of such a law in order for the government to obtain a conviction. Since elective orthopaedic operations, such as knee arthroscopy, total joint arthroplasty, and spinal disc excision are high-volume operations that may be done in surgeon-owned

facilities, the profession is particularly likely to attract scrutiny by government payers.

Expanding Criminal Liability

Previous federal prosecutions under § 1347 have targeted parties whose actions were clearly fraudulent, such as submitting bills for operations that were never done, or billing for implants that the patient did not receive. The bright line separating criminal from noncriminal conduct in such cases is relatively clear. However, a 2013 court opinion in *United States v McLean* suggests that the government is willing to expand § 1347 to target surgeons who perform and bill for operations deemed medically unnecessary [9]. In *McLean*, a cardiologist was convicted of performing a high volume of coronary stent placements in arteries with less than 70% stenosis. The *McLean* verdict is concerning for orthopaedic surgeons because it provides little guidance to physicians to distinguish between criminal negligence and civil malpractice, at least with respect to the application of a permissive approach to indicating medical procedures.

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Is the Hospital Culpable?

The *McLean* ruling also did not identify the culpability, if any, of the hospital where the unnecessary operations were done. That hospital gained financially by independently billing payers for unnecessary coronary stents. Hospital liability in civil malpractice cases related to medical negligence was established by the 1965 legal decision, *Darling v Charleston Community Memorial Hospital* [2]. In *Darling*, an 18-year-old patient lost a limb from a delayed diagnosis of compartment syndrome [2]. The hospital argued that it could not be responsible for the acts of independent hospital staff members who were not employees. The court held instead that the hospital had a duty to its patients to monitor the care provided even by nonemployed physicians who were members of its medical staff. Since *Darling*, medical malpractice actions against physicians can also name the hospital as a defendant, on the grounds that the hospital failed in its oversight duty to monitor and regulate the quality of healthcare provided by the physician.

To our knowledge, no legal ruling has yet implicated a hospital or its administrative staff for criminal activity of a healthcare provider when that activity also generated revenues for the hospital. This is likely because the

government has limited itself to civil, monetary penalties against offending institutions, rather than charge hospital administrators with criminal indictments.

But will the government try to expand liability? It is instructive to examine related legal cases. In the medical-device industry, for example, in 2011 the government successfully convicted senior corporate executives at Synthes Inc. for the improper marketing and promotion of a bone cement product, contrary to the food and drug laws [6]. In seeking prison terms for the offenders, prosecutors invoked the so-called responsible corporate officer doctrine, which holds executives in certain positions of authority criminally liable for violations of food and drug laws, even if they lack direct knowledge of the alleged misconduct.

Willful Blindness

If the government decided to target hospitals that benefit financially from unnecessary surgery, the relevant legal doctrine may be one called “willful blindness.” That doctrine was clarified in the 2011 US Supreme Court ruling in a case titled *Global-Tech Appliances Inc. v SEB S.A.*, a patent-infringement dispute [5]. The issue before the court was whether a party who knew that a patent existed could induce infringement of that patent by

another party, while professing ignorance that the patent existed. The court held that to find that a party had engaged in such willful blindness, two threshold requirements must be met. First, the defendant must subjectively believe that there is a high probability that a fact exists, and second, the defendant must take deliberate actions to avoid learning of that fact. Thus, “a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts,” according to the court [3].

Willful blindness, invoked in *Global-Tech*, may expose hospitals to health-fraud prosecutions, whereby the government accuses a hospital or surgery center as a coconspirator in the performance of unnecessary operations. Some elective operations are now believed to have little, if any patient benefit. As an example, one large multicenter, longitudinal cohort study suggested that at least one-third of all total knee replacements are done for inappropriate indications, and if that is found broadly to be the case, they might be considered unnecessary [9]. Likewise, several well-designed clinical trials have shown that knee arthroscopy for a degenerative medial meniscus tear is not medically necessary, with no patient benefit over placebo surgery.

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Rationale for Expanding Hospital Liability

There are strong reasons for the US Justice Department to expand criminal liability to include hospitals that benefit from the apparent and continuous performance of unnecessary tests and procedures in the facilities. One reason is that healthcare costs related to fraudulent activity by providers remains a concern for the government. The second reason is deterrence; prosecutors have clarified that their primary goal is to discourage similar behavior by other health care providers. In one recent criminal conviction of a Detroit-based spine surgeon for improper billing practices, prosecutors remarked that as of 2015, the Eastern District of Michigan had become a hotbed for “criminal medicine,” with some 300 individuals indicted on Medicare fraud charges since 2009 [8]. Similarly, in the conviction of Synthes executives, the Justice Department successfully obtained lengthier prison terms than those specified under federal sentencing guidelines, partly to deter other healthcare industry executives. The threat of criminal penalties—specifically, prison terms—for healthcare executives would be the strongest possible deterrent in the government’s fight against what it perceives to be healthcare fraud.

The possibility of criminal sanctions is a compelling incentive for hospitals to set in place enhanced utilization and peer-review processes, designed to identify potential emerging healthcare fraud involving unnecessary treatments. There are advantages for physicians in supporting such hospital oversight and utilization review functions. If these efforts can identify healthcare providers with unusually high volumes of elective surgery whose patient benefits are debatable, then timely intervention may help avoid a government investigation.

Because the definition of what constitutes an unnecessary operation may be elusive, a hospital-utilization process may be an effective tool to help identify patterns of unnecessary treatments that fall outside the norm, and that could create criminal exposure for medical staff members. In this regard, a hospital utilization process could help identify an outlier surgeon, before criminal exposure is created for the surgeon. Robust monitoring can also serve as a defense to a surgeon wrongfully accused of criminal conduct simply because he or she is an outlier in the aggregate sum of billings. Rather than receive a target letter or criminal complaint from the government as an antecedent to an indictment, it is far preferable if the initial notification of a concerning pattern of unnecessary treatments is

from within the hospital or healthcare community to allow for timely changes in clinical practice patterns. The healthcare community should understand that it is far better to pre-empt criminal prosecution by demonstrating its responsibility in resource monitoring than ignoring this responsibility and leaving it to the Justice Department to determine which physicians, surgeons, or institutions should be criminally sanctioned for their egregious use of limited healthcare resources.

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