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HEALTH CARE FRAUD

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CERTIORARI

Supreme Court asked to weigh in on 'legal falsity' theory under FCA

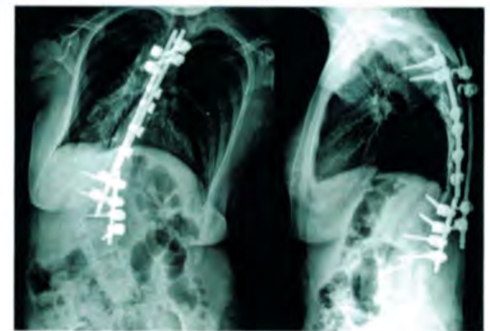
A medical device provider is asking the U.S. Supreme Court to decide the scope of allegations of the "legal falsity" theory of liability under the False Claims Act.

***Blackstone Medical Inc. v. United States ex rel. Hutcheson*, No. 11-269, petition for cert. filed (U.S. Aug. 30, 2011).**

A split among the circuit courts mandates that the high court settle the conflict, Blackstone Medical Inc. says.

The premise of the legal-falsity theory is that although claims submitted to the government may be factually accurate, they are legally false because they expressly or implicitly represent a false compliance with regulatory requirements.

Blackstone markets and distributes spinal implants and other surgical products. In 2004 a former employee filed a *qui tam* suit in the U.S. District Court for the District of Massachusetts, alleging the company violated the federal anti-kickback statute, 42 U.S.C. § 1320a-7b, by paying doctors to use its devices in their surgeries.



A former employee accused the defendant, which markets spinal implants of unlawfully paying doctors to use its products. An X-ray of a spinal implant is shown here.

Blackstone then caused the hospitals where the surgeries were performed to submit "legally false" claims that were tainted by its alleged violation of the anti-kickback statute, the suit said.

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COMMENTARY

Health care reform sets the standard under the federal Anti-Kickback Statute, but how much longer will it apply?

Attorney Craig B. Garner discusses the impact of the recently enacted health reform law on health care fraud laws.

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Health care reform sets the standard under the federal Anti-Kickback Statute, but how much longer will it apply?

By Craig B. Garner, Esq.
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INTRODUCTION

Under its aegis, the 2010 Patient Protection and Affordable Care Act, more commonly referred to as Health Care Reform, Pub. L. No. 111-148, clarified the criminal-intent requirement under the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

Before PPACA, federal courts applied different standards of intent, both general and specific, in determining the existence of violations under the AKS. Section 6402(f)(2) of PPACA amends the AKS by stating, in part:

> With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

Like it or not, congressional design is clear, and this general-intent threshold now serves as the national standard for the AKS after PPACA. While constitutional scholars may take aim at this seemingly benign amendment when they eventually tire of health care reform's individual insurance mandate, health care and criminal law practitioners are better served by understanding the historical landscape leading up to Section 6402(f)(2).

By tracing the evolution of the AKS, as well as the companion False Claims Act, 31 U.S.C. § 3729, and the Ethics in Patient Referrals Act, 42 U.S.C. § 1395nn (more commonly referred to as Stark I and Stark II), practitioners may have a stronger perspective with which to offer their clients advice within the rapidly changing climate of health care reform, rather than relying upon cautionary missives that speak to this watered-down standard of *scienter.*

SOME LEGAL HISTORY

Actus non facit reum nisi mens sit rea. ("The act is not culpable unless the mind is guilty.")[1]

With a few exceptions, historical discussion of criminal law has tended to combine bad actions with a previously existing desire to effectuate the same. Most often in the context of ordinary, visible crimes such as murder, battery, robbery, arson, etc., a common condition precedent to conviction for such offenses was specific intent.[2] This mental element exists as a subset within two separate and distinct types of crimes: those prohibited by statutory authority *(malum prohibitum*, such as parking regulations, copyright laws and the tax code), and those plainly in violation of society's standards (*malum in se*, such as rape and murder).

In the 20th century, a new species of violation emerged, coined by professor Edwin Hardin Sutherland as "white-collar crime" in his December 1939 presidential address to the annual meeting of the American Sociological Society. Though challenging at times to identify with specificity, white-collar crimes become easier to understand by examining what most scholars agree they are not, including crimes of force, those relating to illegal drugs, organized crime, immigration and violations of civil rights.[3]

As white-collar criminal legal theory evolved, so did its accompanying standard for *mens rea* (guilty mind), which usually vacillated between general and specific intent, flirted at times with no intent for certain strict liability offenses *(malum prohibitum)*, and avoided almost altogether the highest transgressions of society's standards *(malum in se)*.

SOME HEALTH CARE HISTORY

When President Lyndon Johnson symbolically handed former President Harry Truman the first Medicare card July 30, 1965, the United States and Medicare became inextricably connected. Only seven years later, Congress passed the first of what would be many laws focusing on Medicare reform.

The Social Security Amendments of 1972, Pub. L. No. 92-603, tried to gently regulate Medicare provider fraud and abuse, as well as overutilization and unnecessary referrals, in part to appease a nation still somewhat in disbelief with Medicare's share of 3.5 percent of the 1970 national budget.[4]

Five years later, in 1977 Congress expanded the scope of prohibited conduct under Medicare to include practically any remuneration for a physician from the referral of a Medicare or Medicaid beneficiary. Congress also authorized exclusion from Medicare and Medicaid of any physician convicted of such conduct (Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142).

> The Social Security Amendments of 1972 tried to gently regulate Medicare provider fraud and abuse, as well as overutilization and unnecessary referrals.

In 1980 Congress added a knowledge qualifier so enforcement could focus on providers who "knowingly and willfully" violated the tenets of Medicare and Medicaid (Omnibus Reconciliation Act of 1980, Pub. L. No 96-499). The following year, Congress passed the Civil Monetary Penalties Law, Pub. L. No. 97-35, authorizing the federal government to assess fines as well as program exclusions against providers who submit false, fraudulent or otherwise inappropriate claims to Medicare or Medicaid.

Not surprisingly, these and other related enhancements to the federal government's ability to monitor the integrity of the Medicare program proved somewhat overwhelming for enforcement officials to put into practice. In 1987 Congress enlisted the aid of the Office of Inspector General to clarify what types of provider arrangements were inappropriate (Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93). The result of this inquiry

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was the first of many safe-harbor regulations identifying specific instances that would not be subject to federal prosecution.

In truth, this ongoing, somewhat one-sided discussion between the federal government and health care providers has identified and codified industry standards since the first regulations went into effect in 1972.

Notwithstanding the federal government's focus on prohibiting payment for referrals as a means to its regulatory end, the constant push to reduce provider incentives and limit overutilization had one specific, ultimate objective: contain the rising costs in the Medicare and Medicaid programs.[5]

HANLESTER NETWORK V. SHALALA

Through the mid 1990s, the OIG and federal courts cast a wide net in the enforcement of fraud-and-abuse legislation, distancing themselves from safe harbors that would promote innovation as a means to save health care resources.[6] In 1995, however, the 9th U.S. Circuit Court of Appeals changed the national direction by limiting application of the fraud-and-abuse statute in *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). In order to prove liability under the fraud-and-abuse statutes, the 9th Circuit required defendants to "knowingly" act in violation of the statute and "willfully" "engage in prohibited conduct with the specific intent to disobey the law"[7] — paving a road whereupon defendants could plead ignorance as a defense (*actus non facit reum nisi mens sit rea*).

Since the Hanlester Network decision, the federal circuit courts have generally disagreed on the appropriate standard of intent. Indeed, since the 1970s, federal legislation has been inapposite to the traditional notions of capitalism, motivated in large part by the belief that self-interested remuneration for the referral of Medicare beneficiaries lead to increased costs and over-utilization.[8]

The increase in number of physician-owned specialty hospitals through 2003, ironically advanced by the "whole hospital exception" in Stark I and II, only added to the federal government's steadfast belief that these institutions were an unnecessary drain on the Medicare system.

The 2006 Medicare Payment Advisory Commission report to Congress on physician-owned specialty hospitals only confirmed the federal government's suspicions. In addition to noting that the number of physician-owned specialty hospitals doubled from 2002 to 2004, MedPAC also concluded physician-owned specialty hospitals were no less expensive than community hospitals and were in fact significantly more expensive for orthopedic specialty hospitals.

Furthermore, MedPAC opined that physician-owned specialty hospitals tended to treat more patients with lower acuity than community hospitals, thereby usurping a sizeable market share from community hospitals without treating a significant number of Medicaid patients. MedPAC's follow up report in 2006 confirmed much of the same as its predecessor but added the finding that rates of utilization and Medicare costs increase when a physician-owned specialty hospital commences operations in a community.

MANAGING MEDICARE UNDER THE 2010 PPACA

Health care reform adds about 32 provisions and $350 million relating to fraud-and-abuse, giving the federal government an enormous cache of new weapons as it struggles to uphold Medicare's integrity and provider compliance.[9] With tougher statutes and stiffer penalties, PPACA makes it unmistakably clear that the federal government's intentions are sincere and its minions well-armed, a fortuitous opportunity for federal prosecutors intent on addressing the continuous escalation of health care expenses nationwide.[10]

It is not surprising that health care reform clarified the fact that violations of the AKS constitute liability under the FCA Section 6402(f). Likewise, the statutory reversal of Hanlester Network through PPACA Section 6402(f)(2) was also anticipated. By eliminating the need for prosecutors to prove specific intent in violations of the AKS, providers may now be subject to criminal liability even if they had no intent to violate the fraud-and-abuse statutes. Notwithstanding the constitutional arguments that may eventually gain national attention, perhaps the more immediate and appropriate response by health care practitioners should be: why now?

Since its first attempt in 1972 to restrict perceived abuses to the Medicare system, Congress has focused its energies on creating and maintaining a program that is fiscally sound. In doing so, free-market forces have been largely cast aside as a result of the fact that the federal government has consistently believed an infusion of capitalism would inevitably result in inappropriate referrals done as a means to increase provider remuneration as an unlawful expression of gratitude. The federal government also believes that this leads to overutilization and a drain on the Medicare system.

Erosion of the elements establishing any crime is of concern, especially when it relates to the requisite level of scienter. To be sure, crimes that are statutory in nature (malum prohibitum) can still cause harm (such as those of perjury, tax evasion and prison escape), and few protest the ways in which the government prosecutes these actions. In contrast, however, is the category of "victimless crimes," and scholars do not always agree on the proper course of action, especially when identification of the victim is subjective in nature, such as taking medication without a prescription and parking too far or near the curb. Speeding is another example wherein debate exists as to the nature of the true victim. For example, what if the highway of the future could identify bends in the road and traffic conditions 20 miles in the distance? If this information could be relayed to a vehicle driving in a predetermined safe zone, should prosecution be warranted for exceeding the speed limit by 10 or even 20 mph?

In 1995 the 9th Circuit changed the national direction by limiting application of the fraud and abuse statute in *Hanlester Network v. Shalala*.

While science fiction is seldom a leading argument used by health care practitioners to inspire confidence, the future, on the other hand, should be. At the core of health care reform stands the idea that performance must lead the way toward achieving efficiency, not the cost-based initiatives of the past.[11] Even the historical focus on individual clinicians instead of hospital systems has altered, as PPACA now

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encourages provider collaboration in the form of "accountable care organizations" and bundling. Such "hospital value-based purchasing programs" effectively shifts the reimbursement infrastructure from cost to performance.[12]

PPACA also provides certain mechanisms for CMS to evaluate both patient satisfaction and hospital-quality measures. As a result, in the future hospitals may face a 1 percent reduction overall on Medicare payments under the Inpatient Prospective Payment System as these funds are now earmarked to cover performance bonuses. By 2015, hospitals that continue to show poor performance ratings will not only be excluded from this bonus pool; they will also face additional cuts in reimbursement.[13]

CONCLUSION

Under PPACA, the federal government has the blueprints to transform health care's structure into a program that is performance-based and no longer cost-driven. Indeed, the very market forces that the federal government has deemed unimportant for nearly 50 years now stand to revolutionize the industry, leaving the fate of this nation's almost 6,000 hospitals at the mercy of what people think in relation to their quality of care. While the erosion of the criminal-intent requirement under the AKS is troubling to most providers, it may prove to be short-lived, eventually to be replaced by the expanding performance-based infrastructure of the future. Should this occur, federal regulators are in little danger of becoming unemployed due to these newly enforced quality measurements. Health care entrepreneurs (whether characterized as such either in the pejorative sense or as a compliment) are resilient, to say the least, and it seems unlikely that fraud-and-abuse regulations will ever become obsolete. However, the federal government's historical focus on costs as a means to justify the expansion of their prosecutorial authority may be in its final chapter. Should such a structural transformation come to fruition, Congress may have little choice but to reevaluate the entire body of health care reform, and in particular the changes in the AKS intent requirement pursuant to PPACA Section 6402(f)(2). WJ

NOTES

[1] Coke, Edward, Institutes Part II, Chapter 1, folio 10 (1797 ed.); but *see* 2, Pollock & Maitland, History of English Law 99 (2d ed. 1923) (noting that much older, English criminal law did not require the element of intent, such as the 12th century Leges Henrici Primi (the Laws of King Henry I of England) ("he who commits evil unknowingly must pay for it knowingly").

[2] *See* generally Sir William Blackstone, *Commentaries on the Laws of England* (1765-1769), Book 4, Chapter 2 ("Indeed, to make a complete crime, cognizable by human laws, there must be both a will and an act.").

[3] *See* generally Strader, J. Kelly, Understanding White Collar Crime.

[4] *See* Oberlander, Jonathan, *The Political Life of Medicare*, University of Chicago 2003, pp. 116-120.

[5] *See, e.g.*, Blumstein, James F., *The Fraud & Abuse Statute in an Evolving Health Care Marketplace*, 22 Am J. L. & Med. 205 (1996) ("By prohibiting financial incentives to induce referrals, the anti-kickback law counters abuses to the Medicare and Medicaid programs that are likely to proliferate in a cost-based, fee-for-service health care market.").

[6] *Id.* at 225 (citing *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 29-30 (1st Cir. 1989); *United States v. Greber*, 760 F.2d 68, 69 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985)); *see* also Crane, Thomas S., The Problem of Physician Self-Referral Under the Medicare and Medicaid Anti-kickback Statute, 268 JAMA 85, 90 (July 1, 1992) ("As physicians consider how to react to the changed regulatory and ethical climate on self-referral, they will undoubtedly balance the desire to generate additional income from these deals, the benefits of new services for their patients and the need to maintain their most 'priceless privilege,' the public's trust.").

[7] *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

[8] *See* generally Perry, Joshua E., *A Mortal Wound for Physician-Owned Specialty Hospitals? The Legal and Ethical Prognosis for Market-Driven, Entrepreneurial Medicine in the Wake of 2010 Health Care Insurance Reform* (August 2010) (citing Mitchell, Jean M., *Physician Joint Ventures & Self-Referral: An Empirical Perspective, Conflicts of Interest in Clinical Practice & Research*, 219-317 (1996)).

[9] *See, e.g.*, Gosfield, Alice G., Health Law Handbook, 108 (West 2011).

[10] According to Congressional Budget Office estimates, major health programs accounted for 2.9 percent of the nation's GDP between 1971 and 2010 (averaged). Under PPACA, this figure may increase to as much as 7.1 percent by 2021. *See, e.g.*, Presentation by Douglas W. Elmendorf, Director, Congressional Budget Office, Federal Budget Math: We Can't Repeat the Past (June 16, 2011).

[11] PPACA Section 3022; 42 C.F.R. § 425 (proposed rules as of Apr. 7, 2011).

[12] *Id.; see* also Berwick, Donald M., M.D., *Launching Accountable Care Organizations: The Proposed Rule for the Medicare Shared Savings Program*, N. Engl. J. Med. (Mar. 31, 2011).

[13] *Id.*

Scan this code with your QR reader to view the Hanlester opinion on Westlaw.

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