Rationalizing The Fraud And Abuse Statute

When fraud and abuse laws were written two decades ago, they never foresaw today's health care market restructuring. Here's one solution for eliminating this obstacle to market growth.

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THE HEALTH CARE MARKET, the organizations that deliver health care, and health care payment mechanisms have all changed greatly in recent years and are continuing to change. In contrast, until the recent enactment of the Health Insurance Portability and Accountability Act of 1996 (the Kassebaum-Kennedy legislation), the so-called antikickback provision of the Medicare and Medicaid fraud and abuse statute has remained much as it was in 1977, when it was amended into its present configuration. As interpreted in United States v. Greber and by the U.S. Department of Health and Human Services (HHS), the fraud and abuse law bars conduct intended to induce future referrals—even if those referrals are medically appropriate, favorably priced, and provided at acceptable levels of quality. Moreover, the "intent to induce" need not be the dominant motivation. It need only be a consideration for the conduct to run afoul of the fraud and abuse law. It is no defense that legitimate considerations, on their own, would justify the activity at issue.

In today's health care environment, the significance of the fraud and abuse statute is hard to overstate. Although well intended, the extremely broad interpretation of the law serves as a major potential obstacle to the continued evolution and rationalization of the health care marketplace in response to competitive market forces and pressures to contain costs. Also, depending on how the Kassebaum-Kennedy legislation is implemented, it could inhibit the growth and implementation of Medicare risk contracting and Medicaid managed care initiatives.

In this context, the terms fraud and abuse are intimidating misnomers, making sensible discussion of the complex issues politically sensitive and subject to unfortunate demagoguery. What is at stake...
is not fraud and abuse in any conventional sense—billing for services not performed, performing services not medically warranted, or providing services at inferior levels of quality. Rather, the very premise of the law—that an intent to use even indirect remuneration to induce future referrals is, by itself, illicit—reflects hostility to a market-oriented health care policy, and these fraud and abuse provisions pose major barriers to market-oriented attempts to rationalize the medical care marketplace. Existing legal fraud and abuse doctrine—even after the ameliorating provisions of the Kassebaum-Kennedy legislation—can discourage vertical integration and other forms of cooperative integration that are socially desirable and essential for improving economic efficiency and consumers' welfare in the health care marketplace. The Kassebaum-Kennedy law takes important steps in remedying some of the most glaring concerns, but further reexamination of this component of the fraud and abuse laws is necessary, because these provisions criminalize market-adaptive conduct. Kassebaum-Kennedy does provide a procedure and a framework for further improvements.

Background

The antikickback provision was designed to address the problems of overutilization and cost containment in Medicare and Medicaid. In 1977 those programs paid for hospital services on the basis of costs and paid for physician services on the basis of usual, customary, and reasonable fees. In such a cost-based, fee-for-service health care market, payers have a legitimate concern about the use of payments to induce referrals. When financial incentives stimulate and reward increased use of services, overuse (with its associated increases in program costs) is a likely result. The antikickback provision was enacted to deal with a real issue.

The provision is much less relevant to a managed care system if the providers or plans are at some financial risk for their treatment decisions. In that situation, the payment system itself inhibits overuse and other costly practice modes. Further, in a fully capitated arrangement such as a health maintenance organization (HMO) or other managed care plan, the payer's financial contribution is fixed in advance; how providers or plans allocate the fixed monetary amount is not a primary concern from the payer's perspective, at least with regard to overuse and cost containment. If anything, the concern of governmental payers in such capitation situations is not with excessive use but with insufficient use of services and resources and accompanying doubts about quality of care.

The HHS approach. Although HHS is authorized to establish “safe harbors” from the broad coverage of the antikickback law, the
approach it has taken is to promulgate narrow exceptions to the statute and to refuse to establish any formal administrative mechanism for providing advice in advance with regard to the legal implications of particular circumstances. As a result, practices that encourage cost-effective care, the formation of managed care organizations, innovation in the structure of health care delivery, and the development of efficient relationships among providers are potentially illegal. These practices should be encouraged, not discouraged; however, the overbroad scope of the fraud and abuse law—at least until the enactment of the Kassebaum-Kennedy legislation—has inhibited appropriate, economically adaptive innovations that are beneficial to consumers and governmental payers alike.

**The Medicare payment system.** Traditionally, medical care has been paid for on a fee-for-service basis. This system compensates a health care provider for every service provided to a patient. The financial incentives of this system promote the use of medical facilities and services; the effect of these incentives is limited by the professional ethics of the provider, the willingness of the patient to spend the time necessary for the procedures, and the willingness of the patient or the patient’s insurer to pay for the procedures. If the patient is well insured, the limitation imposed by costs is greatly attenuated, unless the insurer takes an active part in monitoring costs and services provided. Further, if reimbursement is based on cost, the provider has no financial incentive to limit either medical procedures or overhead costs.

As originally enacted, Medicare reimbursed providers on the basis of their costs or charges and placed no limitations on the amount to be reimbursed. In 1983 Congress established the prospective payment system (PPS) with respect to inpatient hospital services. Under PPS, fixed rates are determined in advance according to specific diagnosis-related groups (DRGs). Hospitals have incentives to discharge patients sooner, since a longer stay does not produce more revenue. However, hospitals also have financial incentives to increase the number of patients served through inpatient admissions.

**The Greber Case**

The courts have interpreted the fraud and abuse antikickback provision extremely broadly. The leading case is *United States v. Greber.* Greber held that if one purpose of a payment is to induce future referrals, the antikickback provision has been violated. In Greber, a physician recommended that a Medicare patient undergo a test. That test needed interpretation, and the testing company (owned by a second physician) paid the referring doctor to perform the interpretation. The court assumed that the referring physician was com-
“There are many appropriate payment arrangements that may be considered fraud and abuse violations under Greber.”

petent and actually performed the interpretation. The second physician admitted that one reason for having the referring doctor interpret the test was concern about future referrals. He defended his conduct by stating that the referring physician was competent to perform the task and already had a relationship with the patient. At the same time, the second physician acknowledged his belief that he would not receive future referrals if he did not request interpretations from the referring physician.

The United States Court of Appeals for the Third Circuit upheld the second doctor’s felony conviction for fraud and abuse violation. The inducement need not be a predominant factor, nor must the services provided be inappropriate. Any economic motivation concerning the use of remuneration as an inducement suffices to constitute a violation. Thus, a motivation to develop business among Medicare or Medicaid patients or to assure a flow of such patients is illegal. Yet such types of arrangements are commonplace in the health care marketplace, and they can be beneficial. But the merits or demerits of the arrangement are irrelevant. Unless they fall within a specific safe harbor, all such arrangements are illegal.

■ **Implications.** The breadth of the Greber doctrine is truly breathtaking. There are many appropriate payment arrangements that may be considered fraud and abuse violations. Hospitals purchase physician practices and make payments to recruit physicians. Such arrangements may enable a hospital to compete with another hospital on price and quality. Nevertheless, such practices may be interpreted as fraud and abuse violations since a goal is to develop a flow of patients for the hospital. Another activity that could be inhibited is the integration of various health care providers into larger organizations. The primary goal of such integration might be to deliver a broad continuum of care and thereby to compete for managed care contracts. This type of competition among health care providers, which could promote price competition and encourage the formation of organizations to deliver efficient managed care, might enhance efficiency and reduce costs. In the long run, that should be beneficial to third-party payers and to consumers. Such beneficial results, however, are not defenses to a fraud and abuse prosecution if the inducement of future referrals is even a part of the motivation.

Managed care organizations can be effective in controlling the
costs of medical care. The ninth annual survey of U.S. companies by a benefits consultant showed the first-ever decline in average health care costs per employee in 1994 and an increase of only 2.1 percent in 1995. Much of the credit for the slowdown has been given to HMOs and other managed care entities. Even small businesses reportedly have been able to reduce costs through managed care. Yet the financial arrangements and inducements often needed to reduce costs in managed care networks—for example, the negotiated reduction of fees on the assurance of increased volume—may violate the fraud and abuse law. The current environment creates disrespect for the law because so much commonplace conduct is in fact illegal. However, it is the legal regime that is out of sync with the realities of the marketplace; the marketplace is fostering socially and economically appropriate (albeit illegal) behavior. Enforcement officials typically look the other way. It has been a regime not of law but of prosecutorial discretion.

A possible antidote to Greber. A 1995 decision by the United States Court of Appeals for the Ninth Circuit, The Hanlester Network v. Shalala, may make proof of a Greber violation more difficult to attain. To determine whether the fraud and abuse law had been violated, the Hanlester court asked whether the defendants had acted with the requisite scienter, by “knowingly and willfully” offering or paying any remuneration to induce referrals. Normally, ignorance of the law is not a defense to a criminal charge; a knowing and willful violation is established if a person purposely commits the act he or she is charged with committing. In Hanlester, however, the court went further. It required a showing that the individual defendants (1) knew that the statute prohibited offering or paying remuneration to induce referrals, and (2) engaged in prohibited conduct with the specific intent to disobey the law. Thus, the prosecution must show that defendants knew that their conduct was illegal but continued to act. Ignorance of the law becomes a defense.

If followed by other courts, Hanlester, as a practical matter, could alleviate some of the harshness and maladaptiveness of the fraud and abuse statute. However, the government has not accepted Hanlester, and at least one other court has not adopted it. Moreover, Hanlester only provides relief because of the type of proof of knowledge required. This could prevent first-time prosecutions of innovative arrangements, but once the breadth of Greber becomes clearly understood in the industry and participants are better counseled, Hanlester’s protection may diminish.

Despite Hanlester and its potential ramifications, reforming the relevant provisions of the fraud and abuse statute is still an important priority for facilitating market-adaptive evolution in the health
care marketplace. Unfortunately, such reform is politically unappealing because of the risk of misinterpretation, misunderstanding, and accusations that smack of outright demagoguery. Nevertheless, revising the law as interpreted in Greber is quite clearly in the public’s and consumers’ interest. The Kassebaum-Kennedy legislation marks an important step forward in this regard.

**Safe Harbor Regulations**

In the aftermath of Greber, Congress authorized the establishment of safe harbors from the existing antikickback provisions of the fraud and abuse statute. The idea was that appropriate conduct that nevertheless fell within the Greber fraud and abuse prohibition could be identified administratively by HHS and shielded from the broad proscriptions established by Greber. In response to this authority, HHS has promulgated only narrow exceptions to the statute. These safe harbors leave intact the analytical structure of Greber but carve out carefully delineated and specifically defined exceptions to the Greber mandate. Practices that are outside safe harbors are not automatically forbidden but are subject to the statutory standard.

Even with these safe harbors, however, violation of the technical requirements of the fraud and abuse law appears to be rampant. That there might be no evidence of harm to consumers or to the government from many of these arrangements is irrelevant—there is no requirement for such a finding. Nor does an affirmative showing of cost reduction, improved patient satisfaction, or better outcomes at no additional cost constitute a legal defense to a Greber violation.

**Difficulties of enforcement.** The prevalence of violation is accompanied by a lack of tough law enforcement, both because of the difficulty of proof and also out of a belief that much technically illegal activity is either harmless or downright essential in a market-driven health care environment. This breeds cynical disregard for the law and has turned the modern American medical center into a health care speakeasy.

HHS and the U.S. Department of Justice have enormous prosecutorial discretion and have sought to assure the health care industry that the enforcement authorities will act responsibly. Nevertheless, HHS has repeatedly declined to provide advice in advance on specific proposals. Recently, HHS opposed a proposed legislative revision that would have required that type of advance advisory process. The regime advocated by HHS and the Department of Justice is the antithesis of the rule of law. It invites abuse and misconduct on the part of government by giving enforcement officials vast standardless discretion and a virtually blank enforcement check.
Ease of bringing private-party lawsuits. This potential problem is about to be exacerbated because a federal district court has held that private citizens can bring an action in federal court without the authorization or approval of federal enforcement officials. This allows the pursuit of a suit for civil liability without the restraining influence of a governmental officials exercise of prosecutorial discretion. Thus, in United States ex rel. Pogue v. American Healthcorp, Inc., a United States District Court judge allowed a disgruntled former employee to sue on behalf of the federal government to enforce the antikickback provisions.  

Under the False Claims Act (FCA), a private party, on behalf of the United States, can sue persons who defraud the federal government. The private party who sues under the FCA need not secure government approval; if successful, the private litigant receives a substantial percentage of any recovery generated on behalf of the federal government. This creates a bounty-hunter scenario for public-spirited whistle-blowers.

In the Pogue case, the court held that the private party bringing the action need not show any harm to the government in order to maintain and prevail on an FCA claim. If a private party can sue to enforce the technical provisions of the fraud and abuse law and need not prove any detriment to the government in order to prevail, then even the restraints imposed by the responsible exercise of prosecutorial discretion by government officials will be eliminated. Thus, even in the absence of changed circumstances, there are many good civil liberties reasons to revisit and revise Greber.

Changed Circumstances

Circumstances have changed. In 1977, when the relevant provisions were enacted, DRGs did not exist; hospitals were reimbursed based on costs. Doctors were paid based on usual and customary fees. Capitation and selective contracting were not significant factors in the marketplace. In short, providers called the tune, and payers financed the music at rates essentially set by the providers. In such a cost-based, fee-for-service environment, the utilization-control rationale for the fraud and abuse provisions was clear.

Today millions of Americans are enrolled in HMOs, and provider risk bearing through capitation is increasing dramatically. In markets with a high degree of capitation, such as California, costs or the rate of increase in costs have come down. Networks have developed, vertical integration has taken place, and efficiencies have emerged in response to competition and prudent purchasing practices. Clinical uncertainty exists. Procedure rates vary enormously for no apparent reason. It has been demonstrated that incentives matter. Lengths of hospital stay are down; less costly outpatient services are up.
In this new and evolving market—and as Medicare risk contracting and Medicaid managed care receive greater attention—the Greber-type fraud and abuse law is an overreaching anachronism. It does not recognize that business arrangements premised on steering patients may result in cost savings and quality enhancements yet still run afoul of the fraud and abuse law. Until the enactment of Kassebaum-Kennedy there was no accommodation for capitation or other provider-at-risk arrangements, in which the risk of over-utilization is minimal, and there was no procedure for advisory opinions to guide good-faith compliance. Even after Kassebaum-Kennedy the law still does not consider the economic benefit of an arrangement; there is room only for prosecutorial discretion. Also, there is no requirement for a showing of economic harm to the government from specific activity. On top of this comes the district court’s decision in Pogue holding that any private citizen can sue to enforce the technical requirements of the fraud and abuse law without any restraint by government and without any showing of financial detriment to the government.

Implications of the Kassebaum-Kennedy legislation. These changes in the marketplace suggested to Congress that the existing rules were out of place as providers take on financial risk. HHS offered as reassurance to providers that there had never been any action against an HMO or a preferred provider organization (PPO) arrangement operating in good faith. This “trust-me” approach is small solace for risk-taking innovators who are performing beneficial tasks but who risk running afoul of an anachronistic application of the law. This approach is now particularly subject to question if private parties can bring an FCA action to enforce the antikickback component of the fraud and abuse law. Even without that development, the HHS position was highly questionable from a civil liberties and public accountability perspective, especially in view of the department’s refusal to provide advisory opinions (and its opposition to a statutory requirement of such).

Thus, statutory modification of Greber has been an extraordinarily important step in allowing for the further rationalization of the health care market. The Kassebaum-Kennedy law is an important first step and provides a framework for potential further improvement. The law does at least three important things regarding the antikickback provisions of the fraud and abuse law. First, it provides a broad exception for arrangements in which providers assume significant financial risk for their treatment decisions. This is the most significant (and least controversial) first step in reforming the fraud and abuse law, and Congress mandated fast-track regulatory implementation of this provision. Second, it requires HHS to
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give advisory opinions regarding specific proposals. These opinions are binding on the parties involved but not on others. This reestablishes the rule of law and provides a case-by-case opportunity for the government to determine what structures and organizational arrangements are beneficial. The government then will be in a better position to develop broader, generalized rules that are more widely applicable. This is the familiar common-law process, whereby rules or principles are derived by examining the rationales used over time in deciding on the merits of specific situations. Third, the law establishes a formalized process of accountability in the development of additional safe harbors. HHS is required to solicit proposals for new safe harbors or revisions of existing ones. If the government does not accept a recommendation, it is obliged to explain its rationale in an annual report to Congress. That procedure, in turn, provides a potential vehicle for further refinements of the fraud and abuse law. Possible new safe harbors could specify (1) that inducing future referrals must be a “significant” (and not just any) purpose in the financial arrangements among providers; (2) that reducing Medicare or Medicaid costs is a defense to a prospective fraud and abuse violation in the absence of significant, unacceptable decreases in the level of quality; and (3) that a defense to a prospective fraud and abuse violation is established when improved quality or choice is provided to program beneficiaries at no increased costs.

Legislative modification of the fraud and abuse law as reflected in Kassebaum-Kennedy is an important step in eliminating a potentially large obstacle for market-adaptive conduct among Medicare and Medicaid providers. It facilitates the development of more risk contracting in the Medicare program and the expansion of Medicaid managed care initiatives. And, through its binding advisory opinion requirement, it starts to restore the rule of law to this area of the health care market. Its strengthened safe harbor procedures could contribute to further rationalization of the health care market.

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NOTES


2. The fraud and abuse statute prohibits many clearly illegal actions such as making claims for services that were not provided or for different services than were provided. 42 U.S.C., sec. 1320a-7a. See J.L. Mashaw and T.R. Marmor, "Conceptualizing, Estimating, and Refining Fraud, Waste, and Abuse in Healthcare Spending," Yale Journal on Regulation 11, no. 2 (1994): 455.

3. Other objectives sometimes ascribed to the antikickback provisions are the preservation of patients freedom of choice and the protection of competition. See R.P. Kusserow, "The Medicare and Medicaid Anti-Kickback Statute and the Safe Harbor Regulations—What’s Next?" Exempt Organization Tax Review (March 1993): 419–420. These surely would seem to be subordinate goals of the antikickback ban and should not be viewed as independent objectives of the fraud and abuse law.


5. In enacting the Kassebaum-Kennedy legislation, Congress has now recognized this position, because the new law creates a statutory safe harbor for arrangements in which providers are at risk financially.

6. From the patient's perspective, there is a legitimate concern that the provider's financial interest rather than the patient's best medical interest will drive decision making. This is a well-recognized and appropriate professional/ethical concern with any system that creates financial incentives for providers to constrain costs. See, for example, J.C. Fletcher and C.L. Engelhard, "Ethical Issues in Managed Care: A Report of the University of Virginia Study Group on Managed Care," Virginia Medical Quarterly (Summer 1995): 162, 164–165. At the same time, it is questionable whether the federal fraud and abuse law should have much application to that set of questions. They are generic issues relating to managed care and have typically been addressed by states in their regulation of the practice of medicine. Further, the harsh absolutist approach of the federal fraud and abuse law is fundamentally at odds with the market-oriented use of financial incentives to constrain health care costs. Its use to address these ethical and quality-oriented considerations would call into question all forms of provider-based economic constraints on medical decision making. The antikickback provision should be given narrower scope, leaving to other provisions the appropriate balancing of interests regarding the fiduciary relationship between doctor and patient. In this regard, disclosure requirements and informed consent rules will be fruitful policy pathways to pursue instead of the outright prohibition of financial inducements that are contained in the antikickback provision of the fraud and abuse law.

7. Through the Office of Inspector General, HHS does issue alerts from time to time. These can aid lawyers in providing advice to clients about HHS's current thinking—how it will exercise its prosecutorial discretion—but they do not
have the force of law. Accordingly, these alerts cannot be relied upon without risk; the underlying conduct still may constitute a violation of the law, even if the enforcement agency is disinclined to enforce the law in certain circumstances. This will become an increasing problem if, as at least one federal district court has held, private parties are allowed to sue to enforce the anti-kickback provisions by using the False Claims Act. See United States ex rel. Poguc v American Healthcorp, Inc., 914 F.Supp. 1507 (M.D. Tenn. 1996). Under the Kassebaum-Kennedy legislation, HHS will be obliged to provide advisory opinions regarding the legality of certain transactions and arrangements. These opinions would bind the parties involved. This is an important advance that will provide greater certainty for the industry. The process also will allow HHS to evolve a common law that is more sensitive on a case-specific basis to advantages and disadvantages to particular organizational structures and other institutional arrangements. HHS then will be in a position to approve those that are beneficial and to disapprove those that are not, allowing generalizable principles to evolve from the treatment of specific situations.

8. 760 F.2d 68 (3d Cir. 1985).

9. The facts in Greber were in dispute, perhaps indicating an old-fashioned kickback scheme in which payment was made when no services were performed. Nevertheless, the Third Circuit assumed in its analysis that more was involved than a question of payment for services not provided. The legal doctrine that stems from the ruling in Greber reaches well beyond the dubious practices that might have characterized the behavior under review in the decision itself.

10. For example, an emergency room doctor, hired as an independent contractor, may be in some jeopardy for referring even medically appropriate cases to the hospital that hires him or her if that emergency room doctor (as just one of many other appropriate motivations) worries that failure to refer to the hospital might result in the termination of his or her contract. Although the personal services safe harbor might protect the payment from the hospital (the "principal") to the physician (the "agent"), it would not protect the physician (the "agent") who uses remuneration (referrals to the hospital) to retain the emergency room contract with the hospital. 42 CFR, sec. 1001.952(d). Further, services performed under a principal/agent agreement cannot involve the "counseling or promotion of a business arrangement or other activity that violates any State or Federal law." 42 CFR, sec. 1001.952(d)(6). That provision at least calls into question behavior that otherwise would violate the ban on behavior designed to induce future business. Since the emergency room physician is not an employee of the hospital, the safe harbor for employees would be inapplicable. 42 CFR, sec. 1001.952(i).


12. Conduct otherwise illegal under the fraud and abuse law may be immunized if it falls within the four corners of a safe harbor rule promulgated by HHS.

13. 51 F.3d 1390 (9th Cir. 1995).


15. In July 1991 and November 1992 HHS published as final regulations thirteen safe harbors from the provisions of the fraud and abuse law. In January 1996 HHS adopted revisions to some of the previously promulgated safe harbors. Additional safe harbors have been proposed but have not yet been adopted.