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Timothy Stoltzfus Jost and Sharon Davies

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The Fraud And Abuse Statute: Rationalizing Or Rationalization?

A warning against letting entrepreneurs’ desire for regulatory freedom overrule the need to protect the public.

by Timothy Stoltzfus lost and Sharon Davies

James Blumstein's Commentary articulates the desire of many health care entrepreneurs to be free from the complex web of federal and state regulations that constrain their ability to structure their business relationships as they see fit. Although Blumstein focuses on the bribe and kickback provisions of the Medicare and Medicaid fraud and abuse laws, similar restrictions are imposed by the Stark self-referral law, statutes in more than forty states that prohibit or regulate self-referrals or bribes and kickbacks, and federal tax provisions that control the business relationships of tax-exempt organizations.

Blumstein argues that the bribe and kickback laws were designed to counter the incentives for provision of excessive medical services inherent in fee-for-service medicine and are no longer needed, since managed care has changed these incentives. He further argues that these laws are harmful, since they prevent otherwise efficient relationships.

Rationale for the law. We must remember at the outset that the vast majority of Medicare beneficiaries and Medicaid recipients still receive fee-for-service medicine, where the classic justification for the bribe and kickback prohibition survives.

Further, while it is true that the costs that bribes and kickbacks impose upon Medicare and Medicaid were a major concern motivating the enactment of the prohibition in 1972 and its strengthening in 1977, the prevention of over-utilization is not the only purpose of the ban. Ethical and legal prohibitions against "fee splitting" were in place long before there was any serious public concern about over-utilization, and the House Committee Report that accompanied the 1977 legislation described the law as addressing "practices that have long been regarded by professional organizations as unethical." The Stark II bill, which dramatically expanded the federal prohibition against financial relationships between physicians and entities to which they refer patients, was adopted in 1993, after most of the changes in the health care industry described by Blumstein had already occurred.

An alternative purpose for the bribe and kickback and self-referral laws is to regulate conflicts of interest in the practice of medicine. Physicians act as agents for their patients in making referrals for diagnostic and treatment services. If the primary motivation of referring physicians is their own financial interest, then not only the cost and quantity of services, but also the quality of the care provided and the nature of the physician/patient relationship might be affected. The patient is best served if the physician sends a test to the most accurate laboratory, not to the one that will pay the physician the largest kickback for the referral.

An absolute prohibition against conflicts
of interest in health care would, of course, be futile. Any form of payment for professional services creates potential conflicts between the economic interest of the health care professional and the needs of the patient. Rather, the federal bribe and kickback and self-referral prohibitions limit themselves to one of the most troubling situations in which conflicts arise. In addressing these conflicts, however, the bribe and kickback prohibition is a much more finely calibrated tool than the blunt instrument Blumstein describes.

Subtleties of the law.
Blumstein asserts at the outset that the federal bribe and kickback law, as interpreted by United States v. Greber, imposes a blanket prohibition against any “conduct intended to induce future referrals.” As he later acknowledges, this is not a complete description of the law. To be sure, 42 USC, sec. 1320b-7(b) begins with an absolute prohibition against the knowing and willful receipt or payment of remuneration in exchange for referrals of Medicare or Medicaid patients. But this prohibition is subject to several exceptions found in the statute itself, including broad exceptions for discount and employment relationships. The statute further authorizes the Office of Inspector General (OIG) to promulgate “safe harbor” regulations to place certain conduct facially violative of the statute beyond the reach of criminal or administrative sanction. The OIG has promulgated several such safe harbors, covering, for example, personal services contracts (an exception that would cover the hospital emergency room/physician relationship described in Blumstein’s Note 10) and managed care contracting. The OIG also has repeatedly emphasized that the safe harbors do not exhaust the range of possible lawful arrangements.

Equally important, the intent requirement of the statute, particularly as recently interpreted by Hanlester Network v. Shalala, provides a double measure of security against the possibility of innocents being jailed. Initially, the government bears the traditional heavy burden of proving beyond a reasonable doubt not only that the defendant made or received payments in exchange for referrals, but also that the payment or referrals motivated the defendant’s actions. Furthermore, if Hanlester is followed by other courts, the government also will be required to prove beyond a reasonable doubt that the provider knew that the exchange was unlawful. This extraordinary requirement guarantees that the “pillars of the community” will not inadvertently become felons. By definition, the law can make a felon only out of someone who consciously decides to act criminally.

The law vis-à-vis managed care.
When the bribe and kickback law is read in the context of its exceptions and the intent requirement, the apparent threat posed for managed care is greatly diminished. Managed care often involves situations in which a plan obtains discounts from providers in exchange for the promise of increased patient business, arrangements that would involve a kickback if the referring professional and the referred-to provider were independent. In the managed care context, however, the patient’s primary relationship is with a managed care plan rather than with a health care professional. Patients realize that in selecting a plan they are accepting its providers and its arrangements with those providers. The statute and regulations have for some time acknowledged this, giving health plans wide latitude to enter into employment or personal services contract relationships with health care professionals or price-reduction relationships with contract health providers. Indeed, the statute and safe harbor regulations have encouraged rather than discouraged integration, since the more integrated an organization is, the more likely it is that its internal arrangements will
be exempt from the prohibition.6

The Kassebaum-Kennedy legislation now goes further, opening a sweeping exception for remuneration paid to individuals or entities who provide items or services to Medicare health maintenance organizations (HMOs) or under risk-sharing arrangements. Managed care is not inherently immune from all of the dangers of bribes and kickbacks, however. Some of the worst abuses in Medicare and Medicaid managed care have occurred in marketing, and a blanket managed care exception might encourage further abuses by permitting commission-based remuneration for independent sales agents. On another front, the recent spate of litigation challenging secret discounts granted by providers to Blue Cross plans whose members were required to pay copayments based on nondiscounted prices might have been avoided had the plans observed the limitations found in the managed care safe harbor.7 There remains a residual role for the bribe and kickback prohibition in managed care.

- **Risk of private-party lawsuits.** Providers will find themselves in a riskier environment if private individuals are permitted to bring False Claims Act (FCA) actions based on the bribe and kickback prohibition. The FCA does not on its face extend to bribes and kickbacks, however, and United States ex rel. Pogue v. American Healthcare, Inc. involved only a district court’s preliminary ruling on a motion to dismiss by a district court. No court has yet imposed liability under the FCA for kickbacks. In any event, defendants are rarely found liable in civil false claims actions when the government declines to intervene on behalf of the plaintiff, so health care providers remain relatively secure if the government chooses not to pursue them.

- **Critique of proposed modifications.** In the end, the bribe and kickback laws undoubtedly discourage some efficient business arrangements. But the proposals endorsed by Blumstein come at a high cost. If defendants charged with bribes or kickbacks could defend themselves by arguing that their arrangements resulted in greater efficiency or quality, the ensuing litigation would exceed in complexity even antitrust litigation (where only efficiency is relevant). This would not only dramatically increase the cost of litigating bribe and kickback issues both for the government and for providers, but also would increase uncertainty with respect to the applicability of the law.

Advisory opinions as authorized by Kassebaum-Kennedy will give greater certainty to providers, but since the bribe and kickback law is an intent-based criminal statute, Kassebaum-Kennedy obligates HHS to assume the highly unusual role of evaluating criminal intent through an administrative process. It may prove very difficult to implement.

The fraud and abuse laws surely could be rationalized, but we must be careful that the rationalizations of health care entrepreneurs desiring freedom from regulatory oversight do not result in the destruction of a prohibition that on the whole effectively serves the Medicare and Medicaid programs, their beneficiaries, and the public.

**NOTES**

2. 42 C.F.R., sec. 1001.952(d) and (m).
4. 51 F.3d 1390 (9th Cir. 1995).
5. Although prosecutors are not required to prove that a provider’s sole purpose in entering into a challenged financial arrangement was to induce referrals, the prosecution must offer evidence that the provider intended to reap financial benefit in exchange for the referrals. Were prosecutors required to prove more—for example, that a provider entered into the arrangement with the exclusive purpose of inducing referrals—the law would easily be circumvented.
7. See, for example, McConocho v Blue Cross and Blue Shield of Ohio. 898 F.Supp. 545 (N.D. Ohio 1995).