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A New Fraud and Abuse Paradigm for ACOs: Blurring the Distinction Between Providers and Payers

BY ROBERT BELFORT

Congress has enacted a web of fraud and abuse laws designed to check the rapid growth in the cost of federal health care programs such as Medicare and Medicaid. These fraud and abuse laws are rooted in the policy concerns raised by the fee-for-service reimbursement system, which has been the predominant mechanism for compensating health care providers.

If the federal government is going to be successful in spawning the development of accountable care organizations ("ACOs") and moving the health care system toward other value-based payment models, a new fraud and abuse legal framework will be necessary. This framework will likely involve viewing health care providers more like health plans under the fraud and abuse laws.

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The Current Fraud and Abuse Framework

Three primary federal laws address the economic relationships among physicians, hospitals, other health care organizations and patients:

The Stark Law. The Patient Ethics and Self Referral Act,[1] commonly known as the Stark Law, prohibits physicians from referring patients to entities for designated health services covered by Medicare if the physician has a financial relationship with the entity that does not fit within an exception. Entities are prohibited from billing Medicare for designated health services provided pursuant to such referrals. Designated health services include, among other things, inpatient and outpatient hospital services. A financial relationship may consist of an ownership or investment interest, or a compensation arrangement. A compensation arrangement is any arrangement involving the provision remuneration, which is defined as any item of value. Improper intent is not a necessary element of a Stark Law violation.

The Anti-Kickback Statute. The Anti-Kickback Statute makes it illegal for any person to knowingly and willfully offer, pay, solicit or receive anything of value, in cash or in kind, in return for the referral of patients or the purchase or recommendation of items or services covered by a federal health care program.[2] The U.S. Department of Health and Human Services Office of Inspector General ("OIG") has established a number of safe harbors to the statute.[3]

[1] 42 U.S.C. 1395nn.
[2] 42 U.S.C. § 1320a-7b.
[3] 42 C.F.R. § 1001.952.

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While compliance with a safe harbor is not mandatory, if all of the elements of a safe harbor are satisfied, an arrangement is insulated from prosecution. The facts and circumstances of arrangements falling outside the safe harbors are evaluated on a case-by-case basis to determine whether any remuneration was intended, in whole or in part, to induce referrals.

Most courts have held that the statute is violated even if one only purpose of the arrangement, among other legitimate purposes, is to induce referrals.[4]

The Civil Monetary Penalties Law. The anti-inducement provisions of the Civil Monetary Penalties Law (''CMPL'') make it illegal for any person to offer or transfer remuneration to any individual covered by a federal health care program ''that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part . . .'' under such program.[5]

The term ''remuneration'' includes items of value provided for free or at less than fair market value. It also includes the waiver of coinsurance and deductible amounts, except in limited circumstances.[6] OIG has taken the position that items of ''nominal value'' (items worth no more than $10 per item and $50 in the aggregate per patient per year) are exempted from the CMPL.[7] There are also several exceptions to the CMPL, including incentives designed to promote specified types of preventive services.

Many states have adopted similar laws modeled on these statutes. In some cases, these state laws apply not only to services covered by federal health care programs but also to services paid for by private, third-party payers.

Although differing in emphasis and scope, all of the major health care fraud and abuse laws are essentially aimed at restricting two types of potentially abusive conduct by health care providers operating in a fee-for-service environment: the over-utilization of health care services and the selection of treatment modalities or providers based on the desire to increase provider income rather than optimize patient care.

Key Fraud and Abuse Issues Raised by ACOs

The ACO model and many other value-based purchasing initiatives change providers' financial incentives while requiring a new level of practice integration among primary care physicians, specialists and hospitals. Certain aspects of the existing fraud and abuse legal framework are likely to be ill-suited to this environment.

■ ***Promoting Cost Saving Practice Patterns***. One of the key principles of the Anti-Kickback Statute and the Stark Law is that the compensation paid by hospitals to physicians may not vary with or otherwise take into account the volume or value of the physician's referrals to the hospital.[8] This restriction is designed to prevent abuse in a fee-for-service system in which a hospital's financial success may be linked to increasing referrals from physicians.

In an ACO environment, however, hospitals may seek to reward their physicians for preventing unnecessary hospital admissions, tests and procedures. There is a narrow exception to the Stark Law that permits *health plans* to financially reward providers for controlling the cost of referral services.[9] But no comparable authority clearly exists for a hospital or a hospital-affiliated ACO to offer similar incentives to physicians participating with the hospital in an ACO. [10]

■ ***Controlling Referral Patterns.*** One of the primary challenges of the Medicare shared savings model contemplated by the ACO statute is that patients are not required to receive their care from the providers in the ACO's network. As a result, ACO participants are at risk that they will end up taking financial responsibility for the cost and quality of medical care delivered by providers that are not obligated to follow the ACO's clinical protocols and care management techniques. This risk naturally focuses ACO members on ways of limiting this ''leakage'' out of the ACO's network. But the fraud and abuse laws generally restrict providers from directly regulating the referral patterns of other health care organizations with which they interact.

The current Stark Law contains a narrow exception that allows hospitals to require physicians to refer to them in connection with employment and other service arrangements. Managed care organizations have been granted similar authority.[11] These exceptions, however, may not be broad enough to permit the type of mandated in-network referral arrangements among primary care physicians, specialists and hospitals that many ACOs will deem essential to their success. As a result, CMS may have to grant ACOs the same flexibility as managed care organizations to dictate referral patterns.

■ ***Influencing Patient Behavior***. While the ACO model is largely premised on a change in the behavior of health care providers, successful ACOs will also need to influence the way in which patients manage their own health. The patient-focused initiatives of innovative ACOs may include efforts to encourage patients to better utilize primary care and preventive services, live healthier lifestyles and participate in organized care management programs.

In an ideal world, all patients would enthusiastically engage in these activities without external motivation. Prior experience suggests, however, that many patients will be more responsible partners in managing their own health care if they are rewarded financially for doing so.

Indeed, the rapid growth in *health plan*-based wellness programs indicates that health care payers believe patient financial incentives are a powerful tool in controlling medical costs. While the Patient Protection and Affordable Care Act (the ''ACA'') expressly expands the

[4] *See United States v. Katz*, 871 F.2d 105 (9th Cir. 1989); *United States v. Bay State Ambulance & Hospital Rental Service, Inc.*, 874 F.2d 20, 29-30 (1st Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied* 474 U.S. 988 (1985).

[5] 42 U.S.C. § 1320a-7a(a)(5).

[6] Coinsurance and deductible waivers are permissible only if the waiver (i) is not advertised, (ii) is not granted routinely and (iii) is provided only after a determination of financial need or an inability to obtain payment after reasonable collection efforts.

[7] 65 Fed. Reg. 24400, 24410 (April 26, 2000).

[8] *See, e.g.*, 42 C.F.R. §§ 411.357(c) and (d).

[9] *See* 42 C.F.R. § 357(d)(2).

[10] Financial incentives to reduce the cost of referral services also implicate a provision of the CMPL that prohibits hospitals from inducing physicians to limit medically necessary services. 42 USC § 1320a-7a(b).

[11] 42 C.F.R. § 411.354(d)(4)

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authority of health plans to offer patients wellness incentives, no comparable power is conferred on providers participating in ACOs.[12] Instead, the ACA delegates to OIG the right to establish any other exception to the CMPL ''which promotes access to care and poses a low risk of harm to patients and Federal health care programs.''[13] Whether acting under this grant of authority or the waiver powers created under the ACO provisions of the ACA, the federal government will have to create additional flexibility for health care providers to influence patient behavior.

If ACOs are going to be successful, the new anti-inducement framework will have to permit a wider range of incentives than those currently allowed under the CMPL's nominal value and preventive services exceptions.

The Need for a New Paradigm

The issues described above share a common theme. Historically, health plans have been afforded flexibility to offer physicians financial incentives designed to control medical expenses, require participating providers to refer within the plan's provider network and induce patients to engage in healthy behaviors.

Hospitals and other providers, however, have faced severe limitations on their ability to engage in similar activities. This distinction made sense in a world where providers were generally paid based on the volume of their services and health plans were paid fixed amounts for a set package of benefits.

But ACOs—whether through shared savings, partial capitation, or full capitation arrangements—will operate under incentives similar to those that have historically guided health plans. As a result, the new fraud and abuse framework governing providers participating in ACOs will have to look more like the framework currently applicable to health plans.

CMS and OIG will have to address this challenge through changes to or waivers of the Stark Law, the Anti-Kickback Statute and the CMPL. State regulators will have to make conforming changes to state fraud and abuse laws.

The status quo of regulating providers and health plans in entirely different ways will almost certainly serve as an impediment to effective ACO development.

[12] ACA § 2705.
[13] ACA § 6402.