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HEALTHCARE

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The Stark Law: Time for a Change?

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The Stark Law

The Stark Law is simple in concept – but maddeningly complex in its application. The Stark Law prohibits physicians from referring Medicare and Medicaid patients for the provision of certain designated health services to a provider with which the physician (or an immediate family member) has a financial relationship. Providers may not bill the federal health care programs for any service which is provided in violation of this prohibition.

The purpose of the Stark Law is to eliminate financial incentives for over-utilization. Although the Law was intended to provide a "bright line" test, there are few bright lines with regard to application of the Law. In fact, the regulations governing application of the Stark Law have become so voluminous and complex that the Law's author, Representative Pete Stark of California, and various former OIG attorneys who helped draft the regulations, have expressed regret about the adoption of the Law and the proliferation of regulations.

As initially conceived, the Stark Law was intended to prohibit physician ownership of certain ancillary services, such as clinical laboratories, diagnostic imaging facilities, durable medical equipment companies, etc. The Law was adopted in response to numerous studies which indicated that such ancillary services were subject to over-utilization when the referring physician had a financial interest in the service. The actual impact of the Stark Law has been not only to limit physician ownership of such ancillary services, but also to prohibit certain beneficial relationships between physicians and hospitals.

The Stark Law is structured as a general prohibition of referrals from a physician to an entity with which the referring physician has a financial relationship. The general prohibition is subject to a wide range of exceptions, some of which are extremely

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complex and contain numerous specific requirements. Failure to achieve 100% compliance with an applicable exception will cause a referral to be in violation of the Law. It is the various exceptions and the specific requirements of each exception which make compliance with the Law complex and difficult.

Impact of the Law

The American Health Lawyers Association (AHLA) recently published a White Paper, analyzing the impact of the Stark Law, and making recommendations for change (August 10, 2009). The AHLA found that, although the Stark Law's basic prohibition is directed at physicians, the impact of the Law falls primarily on hospitals and other institutional providers to which physicians refer patients. If an institutional provider accepts patient referrals in violation of the Stark Law, the institution could be required to return Medicare reimbursement payments and to pay additional penalties under the False Claims Act, even if the violations were unintentional and inadvertent. Moreover, the AHLA suggested that non-compliance with the Stark Law is inevitable because of the Law's complexity and its strict liability provisions, and that the financial consequences of non-compliance can be grossly disproportional to the nature of the conduct which resulted in the violations. If an inadvertent violation goes undetected for a significant period of time, the amount of money which a provider would be required to return to the Medicare program could be substantial, and the obligation to return such amount could have disastrous financial consequences for the provider.

Further, the Stark Law's general prohibitions and the specific requirements of the applicable exceptions make it difficult for providers to work together to develop or implement various arrangements designed to improve health care quality and control costs, such as integrated delivery systems, pay-for-performance arrangements, gain-sharing arrangements, or bundled payments. The regulatory structure of the Stark Law, if left unchanged, will be a direct impediment to two principal objectives of the current health care reform initiative – improving quality and managing costs. Cooperative arrangements among various providers will be necessary to improve the quality of care provided to patients across a range of providers and to control the cost of such care. The Stark Law, and the numerous state self-referral laws which are patterned after the Stark Law, are based upon the assumption that cooperative arrangements among health care providers may create incentives for over-utilization. Thus, the various self-referral laws seek to discourage such cooperative arrangements. The Stark Law and state self-referral laws must be modified in order to permit the type of cooperative arrangements among providers which are necessary to improve the quality of health care services and to control the cost of care.

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In addition, providers are spending substantial amounts of money for legal advice regarding compliance with the Stark Law's complex provisions and addressing the inevitable compliance failures. Providers are also paying substantial sums to valuation firms for fair market value opinions, which are often necessary in order to comply with the requirements of various exceptions to the Law's prohibitions. A more effective regulatory structure would promote spending on prevention, wellness and disease management rather than on the structuring of provider relationships to avoid violation of self-referral laws.

Proposals for Change

To address the perceived problems caused by application of the Stark Law, the AHLA has proposed a number of changes to the Stark Law. One suggestion was that the scope of the Law be limited, and compliance be made easier, by revising the structure of the Law to prohibit only certain specified relationships, such as physician ownership of clinical laboratories, outpatient diagnostic imaging facilities, and similar ancillary services which may be particularly subject to over-utilization, rather than setting forth a blanket prohibition of referrals if there is a financial relationship between the parties, and then identifying a series of specific exceptions. Other suggestions included giving CMS discretion with regard to imposing penalties, or providing for fines rather than prohibiting billing for all services provided in violation of the Law.

It is unlikely that any of the recommended changes will be made to the Stark Law in the near future. Although some of the suggested changes could be implemented through the adoption of regulations by CMS, most of the important changes would require action by Congress. At the present time, Congress is absorbed with comprehensive health care reform legislation and apparently has neither the time nor the inclination to tinker with existing self-referral laws.

To the extent the Stark Law, as currently drafted and enforced, is seen as adding unnecessary cost and complexity to the health care system and impeding implementation of various reforms intended to improve quality and manage costs, at some point in the future, Congress may see fit to address the flaws in the Stark Law. For the time being, however, providers will continue to struggle with interpreting and complying with the complex provisions of the Stark Law as it currently exists.

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